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**A COST AND OUTCOME ANALYSIS OF KIDNEY TRANSPLANTATION:
THE IMPLICATIONS OF INITIAL IMMUNOSUPPRESSIVE PROTOCOL AND DIABETES
(FINAL REPORT: VOLUME II)**

Roger W. Evans, Ph.D. (Co-Principal Investigator)
Diane L. Manninen, Ph.D. (Co-Principal Investigator)
Claudia Thompson, B.S.

Federal Project Officer: Paul Eggers, Ph.D.

Health and Population Research Center
Battelle Human Affairs Research Centers
4000 N.E. 41st Street
Seattle, Washington 98105
Ph (206) 525-3130

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CHAPTER 12

HOSPITAL CHARGES

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CHAPTER 12 HOSPITAL CHARGES

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Introduction

Not only is kidney transplantation regarded as clinically superior to dialysis in the treatment of end-stage renal disease, it is generally considered to be the most cost-effective treatment as well. (Garner and Dardis, 1987:25; Blommers et al., 1984:15; Task Force on Organ Transplantation, 1985; Evans et al., 1985:553; 1987; Manninen and Evans, 1987:269; Schersten et al., 1986:545; Chetwynd and Swainson, 1987:247; Spital et al., 1987:396; Henry et al., 1985:533; Keown and Steller, 1988:s145; Schippers and Kalff, 1976:86; Ludbrook, 1981:337; Simmons and Klein-Marine, 1984:320; Salvatierra et al., 1979:1469; Iglehart, 1982:492; Aroesty and Rettig, 1984; Barber and Rettig, 1985:344; Evans, 1987:61; 1985:129; 1986:603; Eggers, 1984:31; Eggers et al., 1984:69). According to Eggers (1988:223), the costs associated with maintaining a patient on dialysis are approximately three times higher than the costs associated with maintaining a renal transplant patient with a functioning graft. Even after considering the costs associated with those patients who experience graft failures and return to dialysis, it is estimated that transplant costs are paid back in about three years (Krakauer, 1985).

In recent years, the use of cyclosporine has had a major impact on transplant costs (Krakauer, 1985; Henry et al., 1985:533; Manninen and Evans, 1987:269; Barber and Rettig, 1985:344; Evans and Manninen, 1987:1472; 1988:49). Whereas the annual cost of conventional immunosuppressive therapy (prednisone and azathioprine) was approximately \$1,000 to \$2,000 per patient, the National Task Force on Organ Transplantation (1985) estimated the annual cost of cyclosporine therapy (cyclosporine and low dose steroids) to be between \$5,000 and \$8,000 per patient. However, cyclosporine therapy has been credited with dramatic improvements in graft survival, decreases in the

number of rejection episodes, and reduced rates of infection when compared with conventional immunosuppressive therapy. Since patients experience fewer posttransplant complications, subsequent hospital utilization may be lower. Thus, some of the increased cost associated with the new drug are offset by the cost savings associated with a shorter initial hospital stay, as well as fewer posttransplant admissions.

The major medical expenses associated with renal transplantation include hospital costs and the costs of their immunosuppressive drugs. In this chapter we focus our attention on the hospital costs of the 396 transplant patients who were included in this study. The costs examined include: (1) transplant procedure costs (i.e. costs of the initial hospital stay), and (2) hospital costs during each of the follow-up periods.¹ A detailed examination of immunosuppressive drug costs is presented in Chapter 13.

Before proceeding with this discussion, it is important to underscore the fact that this analysis focuses on actual hospital charges, not Medicare-reimbursed costs. Kidney transplants are, of course, covered under the End-Stage Renal Disease Program and are prospectively reimbursed under DRG-302. Medicare does not reimburse hospitals for actual charges. Therefore, the figures reported here may seem inordinately high, given other published reports on actual Medicare reimbursements (or costs to Medicare). In fact, the real value of an analysis of charges lies in our ability to determine the approximate shortfall between charges and costs. If the shortfall is

¹ Like most past studies of transplant costs, this study relies on reported hospital charges. In reporting transplant costs, an estimate of the true costs of the resources used is desirable. Ideally, in well-functioning competitive markets this could be measured by the market prices of the resources used. However, in the U.S. hospital industry, the charges, which are effectively list prices for various hospital services, are unlikely to be an accurate reflection of the actual costs of resources used.

substantial (i.e., Medicare reimbursements are substantially less than hospital charges) a case could be made for calibrating the DRG for kidney transplants. Unfortunately, our original interest during the conduct of this study was to link our hospital charge data with Medicare reimbursement data on a patient-specific basis to analyze the difference. However, time did not permit us to perform the analysis under this grant. We do hope to conduct this analysis at a later date.

Data for our analysis were obtained directly from transplant center billing records. The Baseline Medical Records Data Abstraction Form was used to obtain a complete breakdown of charges for each patient's transplant surgery. Charges for the kidney transplant were broken down into several categories including laboratory tests, diagnostic tests, pharmacy, blood administration, operating room and anesthesia, room and board, and professional fees. The Follow-up Medical Records Information Forms, which were completed at three-month intervals following transplant surgery, were used to obtain similar information for hospital stays during the follow-up data collection period.

In Chapter 7 we observed that patients who initially received azathioprine, prednisone, and antilymphocyte globulin (AZA + PRED + ALG) had better renal function and fewer adverse reactions to cyclosporine than patients who initially received cyclosporine and prednisone (CSA + PRED). In this chapter we examine transplant procedure charges, as well as hospital charges during the follow-up data collection period, for these two initial immunosuppressive protocol groups. As in previous chapters, we also examine the transplant procedure charges and follow-up hospital charges of patients grouped by primary renal diagnosis (diabetes versus nondiabetes). Finally, in

examining transplant procedure charges we examine charges for patients who were discharged from the hospital with a functioning graft compared with patients who were discharged from the hospital dead or with a failed graft. Similarly, in examining follow-up hospital charges, we compare the hospital charges of patients who experienced a graft failure or died during the follow-up period with patients whose grafts were functioning at the end of the period.

Transplant Procedure Charges

The Baseline Medical Records Data Abstraction Form was used to obtain a complete breakdown of charges for each patient's transplant surgery.

Charges for the kidney transplant were broken down into the following cost categories:

- Medical/surgical/central supplies
- Operating room and anesthesia
- Pharmacy
- Laboratory tests
- Radiology/nuclear medicine
- Other diagnostic tests
- Blood administration
- Oxygen and gas mixtures
- Physical, vocational and respiratory therapy
- Dialysis
- Professional fees
- Room and board
- Histocompatibility testing
- Donor kidney acquisition charge
- Other costs

Considerable time and effort was spent obtaining complete transplant procedure charges. The bulk of the information was directly abstracted from the patient's hospital bill. However, depending on the transplant center, it was often necessary to consult various other sources to obtain information

regarding some charges (for example, professional fees) that are billed separately.

For the 396 patients included in the study the mean transplant procedure charge was \$41,045.82. Of course, there was a large variation in total transplant charges. Total transplant charges ranged from a minimum of \$18,483.97 to a maximum of \$727,391.75. The tremendous variation in transplant procedure charges largely reflects differences in the length of the hospital stay. Of the 396 transplant procedures performed, the length of stay ranged from 6 to 252 days. However, other factors, besides length of stay, also influence transplant procedure charges.

Transplant procedure charges by initial immunosuppressive protocol are summarized in Table 12-1. As noted in Chapter 5, the length of the initial hospital stay did not vary for the two initial immunosuppressive protocol groups. Patients who initially received AZA + PRED + ALG were hospitalized an average of 21.6 days, compared with an average of 22.4 days for patients who initially received CSA + PRED. However, patients who initially received CSA + PRED had considerably higher transplant procedure charges than patients who initially received AZA + PRED + ALG. As can be seen in the Table 12-1, total transplant procedure charges at those centers that initially administer AZA + PRED + ALG averaged \$37,473, while at those centers that initially administer CSA + PRED total transplant charges averaged \$47,680.

Moreover, there are interesting differences between the two initial immunosuppressive protocol groups with respect to the average charges for the various cost categories shown in Table 12-1. For example, the pharmacy charges of patients who initially received AZA + PRED + ALG averaged \$6,539--over twice the average of \$3,155 for patients who initially received

Table 12-1
Transplant Procedure Charges by Initial
Immunosuppressive Drug Protocol

Cost Category	Drug Protocol	
	AZA + PRED + ALG	CSA + PRED
Medical/Surgical/Central Supplies	\$768	\$963
Operating Room and Anesthesia	2,887	2,618
Pharmacy	6,539	3,155
Laboratory Tests	3,156	7,774
Radiology/Nuclear Medicine	756	2,625
Other Diagnostic Tests	139	206
Blood Administration	426	707
Oxygen and Gas Mixtures	31	32
Physical, Vocational and Respiratory Therapy	81	915
Dialysis	597	1,652
Professional Fees	6,394	7,625
Room and Board	6,788	9,171
Histocompatibility Testing	2,120	907
Donor Kidney Acquisition Charge	6,735	9,296
Other	56	34

Total	\$37,473	\$47,680

CSA + PRED. On the other hand, the CSA + PRED patient group had much higher charges for laboratory tests and for radiology/nuclear medicine than did the AZA + PRED + ALG patient group. As shown in Table 12-1, the combined charges for laboratory tests and radiology/nuclear medicine for patients who initially received CSA + PRED was, on average, \$10,399 compared with only \$3,912 for patients who initially received AZA + PRED + ALG. When compared with patients who initially received AZA + PRED + ALG, the patients who initially received CSA + PRED also had higher average charges for dialysis and for physical, vocational and respiratory therapy. In addition, CSA + PRED patients had higher charges for professional fees and higher hospital room and board charges than did AZA + PRED + ALG patients. Finally, when compared with patients who initially received AZA + PRED + ALG, patients who initially received CSA + PRED had higher donor kidney acquisition charges and lower charges for histocompatibility testing. However, when the histocompatibility testing and donor kidney acquisition charges are combined, the average charge for the CSA + PRED patient group (\$10,203) was higher than the average charge for the AZA + PRED + ALG patient group (\$8,855).

Having observed differences in transplant procedure charges by initial immunosuppressive therapy, we next turned our attention to the question of whether or not transplant charges varied by primary renal diagnosis. As shown in Table 12-2, there was little difference in average transplant charges of diabetic and nondiabetic patients. This is true for total charges, as well as for the various cost categories. The average transplant charges for nondiabetic patients in the study was \$41,587. For diabetic patients the average transplant charges were \$39,718.

Table 12-2
Transplant Procedure Charges by Primary Renal Diagnosis

COST CATEGORY	PRIMARY RENAL DIAGNOSIS	
	NON-DIABETES	DIABETES
Medical/Surgical/Central Supplies	\$801	\$938
Operating Room and Anesthesia	2,819	2,717
Pharmacy	5,171	5,858
Laboratory Tests	4,832	4,668
Radiology/Nuclear Medicine	1,498	1,190
Other Diagnostic Tests	162	165
Blood Administration	562	425
Oxygen and Gas Mixtures	31	33
Physical, Vocational and Respiratory Therapy	442	192
Dialysis	1,046	759
Professional Fees	6,879	6,685
Room and Board	7,872	6,962
Histocompatibility Testing	1,689	1,697
Donor Kidney Acquisition Charge	7,724	7,410
Other	59	19
<hr/>		
TOTAL	\$41,587	\$39,718

In addition to examining transplant procedure charges by initial immunosuppressive protocol and primary renal diagnosis, it is also interesting to examine transplant charges by discharge status. Table 12-3 presents transplant procedure charges for the following two groups: (1) patients discharged from the hospital with a functioning graft, and (2) patients discharged from the hospital dead or with a failed graft. Clearly, transplant charges varied greatly depending upon the success or failure of the graft. Of the 396 patients included in the study, 378 patients were discharged from the hospital with functioning grafts. These patients had an average hospital stay of 20.5 days and, as shown in Table 12-3, transplant procedure charges for this group averaged \$37,522. In contrast, 18 patients experienced a graft failure during their initial hospital stay (14 of these patients were discharged living and 4 were discharged dead). These 18 patients were hospitalized, on average, 50.9 days and their hospital charges averaged \$115,949. The very high average value associated with this group is, in large part, influenced by one patient with a hospital bill of \$726,691. However, even when this one extreme value is excluded from the calculations, the average transplant procedure charges of this group was approximately \$80,000. Clearly, the hospital charges of patients who were discharged with functioning grafts are considerably lower than the hospital charges of patients whose grafts were not successful.

As shown above, transplant procedure charges vary considerably as a function of the short-term success or failure of the transplant procedure (i.e., the status of the patient upon discharge from the hospital following the transplant procedure). Next, we examined transplant procedure charges to determine the extent to which they are related to the longer-term success or

Table 12-3
Transplant Procedure Charges by Discharge Status

Cost Category	Discharge Status	
	Functioning Graft	Failed Graft
Medical/Surgical/Central Supplies	\$706	\$3,584
Operating Room and Anesthesia	2,646	5,854
Pharmacy	5,081	11,039
Laboratory Tests	4,194	17,260
Radiology/Nuclear Medicine	1,194	6,097
Other Diagnostic Tests	147	502
Blood Administration	391	3,356
Oxygen and Gas Mixtures	30	52
Physical, Vocational and Respiratory Therapy	138	5,363
Dialysis	608	8,572
Professional Fees	6,511	13,465
Room and Board	6,548	30,349
Histocompatibility Testing	1,657	2,402
Donor Kidney Acquisition Charge	7,626	7,941
Other	45	113
<hr/>		
Total	\$37,522	\$115,949

failure of the transplant procedure. All transplant centers were asked to report the status of each participating transplant patient as of July 1, 1987 (from 8 to 20 months following transplantation, depending upon when the transplant procedure was performed). For the purpose of our analysis, patients were then grouped into the following four categories: (1) patients who were living and whose grafts were still functioning, (2) patients who were living but had experienced a graft failure, (3) patients who died with a functioning graft, and (4) patients who died with a failed graft.

As of July 1, 1987, of the 396 participating transplant recipients 328 patients were living with a functioning graft, 46 patients were living and either had received a second transplant or had returned to dialysis, six patients had died with a functioning graft and sixteen patients had died with a failed graft. Transplant procedure charges by status as of July 1, 1987 are shown in Table 12-4.

As shown in Table 12-4, the lowest average transplant procedure charge was associated with the patients who were still living with functioning grafts--the "successful" transplants. The 328 patients in this group were hospitalized for an average of 19.9 days, at an average charge of \$36,488. Patients who had died with functioning grafts had the next lowest average transplant procedure charge. These six patients were hospitalized for an average of 20.8 days and the average charge for these patients was \$43,705. Patients who were still living, but whose first grafts had failed, had slightly higher transplant procedure charges. The average length of stay for the 46 patients in this group was 25.1 days, and the average charge associated with their initial hospital stay was \$47,223. Not surprisingly, patients who died following a graft failure had the highest transplant procedure charges.

Table 12-4
Transplant Procedure Charges by Status as of July 1987

COST CATEGORY	LIVING WITH FUNCTIONING GRAFT (N=328)	LIVING WITH FAILED GRAFT (N=46)	DIED WITH FUNCTIONING GRAFT (N=6)	DIED WITH FAILED GRAFT (N=16)
Medical/Surgical/Central Supplies	\$ 712	\$ 976	\$ 1,089	\$ 2,915
Operating Room and Anesthesia	2,608	3,194	3,314	5,206
Pharmacy	5,143	4,865	4,579	11,348
Laboratory Tests	3,918	6,448	4,651	17,906
Radiology/Nuclear Medicine	1,055	2,051	2,022	6,778
Other Diagnostic Tests	135	210	276	567
Blood Administration	401	526	227	3,194
Oxygen and Gas Mixtures	33	25	8	26
Physical, Vocational and Respiratory Therapy	130	267	198	5,776
Dialysis	503	2,298	375	6,943
Professional Fees	6,364	7,977	7,454	12,763
Room and Board	6,242	8,480	8,679	33,262
Histocompatibility Testing	1,633	1,605	3,526	2,449
Donor Kidney Acquisition Charge	7,562	8,251	7,297	7,627
Other	49	50	10	37
<hr/>				
TOTAL	\$36,488	\$47,223	\$43,705	\$116,797

The 16 patients in this group had an initial hospital stay of 54.3 days and the average cost of the stay was \$116,797.

Follow-up Hospital Charges

In addition to obtaining transplant procedure charges, we also requested data for all hospital stays during each of the follow-up data collection periods. As described in Chapter 2, the Follow-up Medical Records Information Forms, which were completed by a transplant center staff member at 3, 6, 9, 12, and 15-months posttransplant, were used to obtain information regarding hospitalizations following transplant surgery. The first Follow-up Medical Records Information Form covered the period from hospital discharge following transplant surgery until three-months posttransplant. All other follow-up periods were of a three-month duration, unless the patient died or experienced a graft failure during the follow-up period. The data collection coordinator was asked to record the number of times that the patient was discharged from the hospital during the particular follow-up data collection period². For each hospital discharge reported, the data collector was then asked to provide the admission date, the discharge date, and an itemized breakdown of hospital charges for the hospital stay.

With a few exceptions, charges for subsequent hospital stays are provided for the same subcategories as were provided for transplant procedure charges. These exceptions include histocompatibility testing, donor acquisition charges, and professional fees. Histocompatibility testing and donor acquisition charges are not relevant to subsequent hospital stays.

² It should be recognized that if a person was hospitalized at the end of a particular follow-up period, the information was not reported until the next follow-up period--the period during which the patient was discharged from the hospital.

Professional fees, on the other hand, were excluded because in many cases transplant center staff had difficulty obtaining complete information on professional fees, since they are routinely billed separately by each physician. In some cases these charges were unavailable and in many cases we believe that the data provided were incomplete. Thus, in reporting hospital charges for admissions during the follow-up data collection period, we have chosen to report hospital charges excluding professional fees.

Obtaining an accurate estimate of follow-up hospital charges was much more difficult than obtaining an estimate of transplant procedure charges. Not all hospital admissions during the follow-up data collection period were at the hospital where the transplant surgery was performed. The data collector at the transplant center may have had no record of these hospital stays, or in some cases the data collector may have had admission and discharge dates, but may not have been able to obtain an itemized breakdown of the hospital charges. However, as was shown in Chapter 7, information provided by patients concerning hospitalizations during the various follow-up data collection periods was remarkably similar to information reported by transplant center staff. Moreover, information provided by patients regarding hospitalizations during the various follow-up data collection periods indicates that approximately 80 percent of all subsequent admissions were at the transplant center where the transplant surgery was performed. Thus, follow-up hospital charges reported here represent the vast majority of subsequent hospital admissions and we feel rather confident that the data represents a relatively accurate estimate of follow-up hospital charges.

Estimation of Per Patient Follow-up Hospital Charges

In most cases, data collection coordinators were able to obtain itemized hospital charges for hospital admissions during the follow-up data collection period (except, as described earlier, for professional fees). In a few cases, however, hospital charges were unavailable. Therefore, the following steps were taken to estimate follow-up hospital charges:

- (1) The total number of days hospitalized and total hospital charges during each follow-up data collection period were computed for each patient based on information reported on the Follow-up Medical Records Information Forms. The length of each hospital stay was computed by subtracting the admission date from the discharge date and adding one³. If a patient was hospitalized more than once during a given follow-up period the number of days hospitalized and the itemized hospital charges were aggregated across all hospital stays.
- (2) The average charge per day hospitalized (excluding professional fees) was calculated based on those hospital stays for which hospital charge data were available. For those hospital stays for which hospital charge data were available, the average hospital charge per day was obtained by dividing total hospital charges, excluding professional fees, by the total number of days hospitalized.
- (3) The average number of days hospitalized during each follow-up data collection period was calculated based on information reported on the Follow-up Medical Records Information Forms. The average number of days hospitalized was obtained by dividing the total number of days hospitalized (including those hospital stays for which no charge data were reported) by the total number of patients.
- (4) The average hospital charge per patient during each follow-up data collection period was estimated by multiplying the average number of days hospitalized during the data collection period by the average hospital charge per day during the follow-up period.

For purposes of our analysis, separate estimates of follow-up hospital charges were made for patients grouped by initial immunosuppressive protocol, by

³ This was done to avoid situation in which a patient who was admitted and discharged on the same day (i.e., for out-patient surgery) would have a length of stay of 0 days.

primary renal diagnosis, and by status at the end of the data collection period.

Differences by Initial Immunosuppressive Protocol--

Per patient hospital charges during each of the follow-up data collection periods for patients grouped by initial immunosuppressive protocol are shown in Table 12-5. During the first year following transplant surgery, there was considerable variation in per patient hospital charges for patients in the two initial immunosuppressive protocol groups. The difference between the two groups was most apparent during the first six months posttransplant. As can be seen in Table 12-5, per patient hospital charges (excluding professional fees) in the first three months posttransplant were considerably higher for the CSA + PRED patient group (\$7,825) compared with the AZA + PRED + ALG patient group (\$4,466). The rather large difference in per patient hospital charges of the two groups, in part, reflects the fact that CSA + PRED patients spent more nights in the hospital than did AZA + PRED + ALG patients. Patients who initially received AZA + PRED + ALG were hospitalized 5.9 days per patient during the period between initial hospital discharge and three months posttransplant, compared with 7.7 days per patient for patients who initially received CSA + PRED. However, the higher per patient hospital charges also reflect a higher charge for each day hospitalized. Hospital charges were \$753 per day for AZA + PRED + ALG patients compared with \$1,016 per day for CSA + PRED patients.

It should be noted that the differences in per patient follow-up hospital charges lessen with increasing time since transplantation. After the first 12 months posttransplant, there appears to be little difference in the per patient

Table 12-5
Follow-up Hospitalization and Hospital Charges* by Initial Immunosuppressive Protocol

	Discharge to 3 Months Posttransplant AZA•PRED•ALG	Time Period							
		3-6 Months		6-9 Months		9-12 Months		12-15 Months	
		Posttransplant AZA•PRED•ALG	Posttransplant CSA•PRED	Posttransplant AZA•PRED•ALG	Posttransplant CSA•PRED	Posttransplant AZA•PRED•ALG	Posttransplant CSA•PRED	Posttransplant AZA•PRED•ALG	Posttransplant CSA•PRED
Number of Patients	246	125		165	97	89	63	55	32
Number of Hospital Days	1,459	963		404	277	201	193	204	77
Hospital Days per Patient	5.9	7.7		2.4	2.9	2.3	3.1	3.7	2.4
Hospital Charge per Day (\$)	753	1,016		906	1,125	765	1,033	797	1,187
Hospital Charges per Patient (\$)	4,468	7,825		2,218	3,212	1,728	3,165	2,955	2,857

*Hospital charges, excluding professional fees.

hospital charges for the two groups. However, during the first year following transplantation, the per patient hospital charges for the CSA + PRED patient group (\$23,744) were over twice the per patient hospital charges for the AZA + PRED + ALG group (\$10,263).

Differences by Primary Renal Diagnosis--

Per patient hospital charges during each of the follow-up data collection periods for patients grouped by primary renal diagnosis are shown in Table 12-6. As shown in Table 12-6, there was relatively little difference in the follow-up hospital charges of diabetic and nondiabetic patients in the first three months following transplant surgery. During the period between initial hospital discharge and three-months posttransplant, hospital charges, excluding professional fees, averaged \$5,540 for nondiabetic patients compared with an average of \$5,798 for diabetic patients. However, during the period between 3- and 6-months posttransplant, per patient hospital charges for diabetic patients was \$6,200, while for nondiabetic patients hospital charges averaged only \$3,811 per patient. A similar pattern of higher per patient hospital charges among diabetic patients was observed between 6- and 9-months and between 9- and 12-months posttransplant. After the first 12 months posttransplant there appears to be little difference in the per patient hospital charges for the two groups.

Clearly, follow-up hospital charges in the first year posttransplant do vary by primary renal diagnosis. During the period from 3 months to 12 months following transplantation, diabetic patients had much higher per patient hospital charges than did nondiabetic patients. During the first year following transplantation, the per patient hospital charges for diabetic

Table 12-6
Follow-up Hospitalizations and Hospital Charges* by Primary Renal Diagnosis

	Time Period											
	Discharge to 3 Months Posttransplant		3-6 Months		6-9 Months		9-12 Months		12-15 Months			
	Nondiabetes	Diabetes	Nondiabetes	Diabetes	Nondiabetes	Diabetes	Nondiabetes	Diabetes	Nondiabetes	Diabetes	Nondiabetes	Diabetes
Number of Patients	272	99	258	94	194	68	115	37	63	24		
Number of Hospital Days	1,722	700	852	470	289	392	232	162	213	68		
Hospital Days Per Patient	6.3	7.1	3.3	5.0	1.5	5.6	2.0	4.4	3.4	2.8		
Hospital Charges Per Day (\$)	875	820	1,154	1,240	955	1,054	872	919	894	957		
Hospital Charges Per Patient (\$)	5,540	5,798	3,811	6,200	1,423	6,076	1,769	4,024	3,023	2,711		

*Hospital Charges, excluding professional fees.

patients (\$22,098) were considerably higher than the per patient hospital charges of nondiabetic patients (\$12,533). Moreover, it is interesting to note that the higher per patient hospital charges among diabetic patients reflect the fact that, on average, diabetic patients spent more days in the hospital compared with nondiabetic patients. The average charge for each day hospitalized was similar for the two groups.

Differences by Status at the End of the Data Collection Period--

Previously, we observed that transplant procedure costs varied greatly depending upon discharge status (that is, whether or not the patient was discharged from the hospital with a functioning graft). Not surprisingly, the hospital charges of patients who were discharged with functioning grafts were considerably lower than the hospital charges of those whose grafts were not successful. Similarly, we examined per patient hospital charges during each of the follow-up data collection periods for patients grouped by their status at the end of the period. For each follow-up data collection period, patients were divided into two groups: (1) patients who had functioning grafts at the end of that particular follow-up period, and (2) patients who either died or experienced a graft failure at some time during the particular follow-up period. The results of this analysis are presented in Table 12-7.

Clearly, the most important factor underlying hospital charges during a particular follow-up data collection period is whether or not the patient experienced a graft failure and/or died during the period. A total of 24 patients experienced a graft failure or died during the period between initial hospital discharge and 3-months posttransplant. For these 24 patients, hospital charges (excluding professional fees) during this period averaged

Follow-up Hospitalization and Hospital Charges* by Status
at the End of the Follow-up Data Collection Period

	Time Period									
	Discharge to 3 Months Posttransplant		3-6 Months Posttransplant		6-9 Months Posttransplant		9-12 Months Posttransplant		12-15 Months Posttransplant	
	Functioning Graft	Failed Graft	Functioning Graft	Failed Graft	Functioning Graft	Failed Graft	Functioning Graft	Failed Graft	Functioning Graft	Failed Graft
Number of Patients	346	24	339	13	258	4	151	1	64	3
Number of Hospital Days	1,836	584	1,003	319	521	160	376	18	167	114
Hospital Days Per Patient	5.3	24.3	3.0	24.5	2.0	40.0	2.5	18.0	2.0	38.0
Hospital Charges Per Day (\$)	722	1,276	777	2,460	666	1,540	864	1,400	872	947
Hospital Charges Per Patient (\$)	3,835	31,049	2,299	60,365	1,626	61,600	2,151	25,200	1,734	35,986

*Hospital charges, excluding professional fees.

\$31,049 per patient. Of the 346 patients whose grafts were still functioning 3 months posttransplant, hospital charges during this same period averaged \$3,835 per patient. Similarly, during the period from three to six months following transplantation, the per patient hospital charges averaged \$60,365 for the 13 patients who experienced graft failures or died during this period. For the 339 patients with functioning grafts at the end of the follow-up period, per patient hospital charges during the period averaged only \$2,299. This same pattern can be observed for each of the follow-up periods for which data were collected.

Itemized Breakdown of Follow-up Hospital Charges

Having estimated total per patient hospital charges during each follow-up data collection period, we next examined follow-up hospital charges broken down into 12 separate cost categories. These cost categories include: (1) medical/surgical/central supplies; (2) operating room and anesthesia; (3) pharmacy; (4) laboratory tests; (5) radiology/nuclear medicine; (6) other diagnostic tests; (7) blood administration; (8) oxygen and gas mixtures; (9) physical, vocational and respiratory therapy; (10) dialysis; (11) room and board; and (12) other. For reasons discussed above, our analysis excluded professional fees.

The following steps were taken to provide an itemized breakdown of follow-up hospital charges:

- (1) For each follow-up data collection period, the proportion of total hospital charges in each of 12 separate cost categories was calculated. For those hospital stays for which itemized charge data were available, hospital charges in each cost category were divided by the total follow-up charges, excluding professional fees, during the particular follow-up period.

- (2) Average hospital charges per patient in the various cost categories during each follow-up data collection period were estimated by multiplying the total per patient hospital charge during the data collection period by the proportion of the total hospital charge in each cost category during the follow-up period.

For purposes of our analysis, separate estimates of itemized follow-up hospital charges were made for patients grouped by initial immunosuppressive protocol, by primary renal diagnosis, and by status at the end of the data collection period.

Differences by Initial Immunosuppressive Protocol--

Itemized breakdowns of hospital charges, excluding professional fees, during the various follow-up data collection periods for patients grouped by initial immunosuppressive protocol are presented in Table 12-8. Earlier we observed that patients who initially received CSA + PRED had considerably higher follow-up hospital charges than patients who initially received AZA + PRED + ALG, especially in the first 6 months following transplant surgery. As shown in Table 12-8, the major differences between the hospital charges of the two groups in the first six months posttransplant reflect higher charges for laboratory tests for the CSA + PRED patient group, as well as higher room and board charges. During the period between their initial hospital discharge following transplant surgery and three months posttransplant, the per patient charge for laboratory tests was \$2,722 for CSA + PRED patients, compared with only \$777 for AZA + PRED + ALG patients. Similarly, between three and six months posttransplant, charges for laboratory tests were approximately ten times higher for CSA + PRED patients (\$3,044) than for AZA + PRED + ALG patients (\$313). The differences in room and board charges, for the most part, reflect differences between the two groups

Table 12-8
Itemized Breakdown of Follow-up Hospital Charges by Initial Immunosuppressive Protocol

	Time Period									
	Discharge to		3-6 Months		6-9 Months		9-12 Months		12-15 Months	
	3 Months Posttransplant AZA•PRED•ALG	CSA•PRED	Posttransplant AZA•PRED•ALG	CSA•PRED	Posttransplant AZA•PRED•ALG	CSA•PRED	Posttransplant AZA•PRED•ALG	CSA•PRED	Posttransplant AZA•PRED•ALG	CSA•PRED
Medical/Surgical/Central Supplies	\$ 116	\$ 140	\$ 61	\$ 658	\$ 148	\$ 61	\$ 64	\$ 76	\$ 130	\$ 77
Operating Room and Anesthesia	178	125	140	296	131	456	79	158	183	294
Pharmacy	1,089	664	377	1,116	450	244	486	250	538	129
Laboratory Tests	777	2,722	313	3,044	355	921	259	1,171	431	880
Radiology/Nuclear Medicine	232	751	89	792	106	263	93	279	231	291
Other Diagnostic Tests	76	85	46	143	69	61	38	19	62	63
Blood Administration	31	156	13	191	9	22	8	10	112	34
Oxygen and Gas Mixture	4	0	2	0	0	0	0	0	3	0
Physical, Vocational and Respiratory Therapy	53	218	11	620	55	54	5	60	53	94
Dialysis	201	344	46	153	104	148	0	101	207	0
Room and Board	1,634	2,574	746	2,490	780	921	689	1,000	972	929
Other	75	46	7	38	11	61	7	41	33	66
Total Per Patient Charges*	\$ 4,466	\$ 7,825	\$ 1,851	\$ 9,542	\$ 2,218	\$ 3,212	\$ 1,728	\$ 3,165	\$ 2,955	\$ 2,857
Hospital charges, excluding professional fees.										

*Hospital charges, excluding professional fees.

in the number of days hospitalized during the first 6 months following transplantation. As we observed in the case of total per patient follow-up hospital charges, the itemized breakdowns of the follow-up hospital charges of the two initial immunosuppressive protocol groups become quite similar with increasing time since transplantation.

Differences by Primary Renal Diagnosis--

Itemized breakdowns of hospital charges, excluding professional fees, during the various follow-up data collection periods for patients grouped by primary renal diagnosis are presented in Table 12-9. As we observed earlier, there was no difference in the follow-up hospital charges of diabetic and non-diabetic patients in the first 3 months posttransplant. Not surprisingly, the itemized breakdowns of follow-up hospital charges for the two groups during this period were also similar. However, during the period between 3 and 12 months following transplantation, diabetic patients had considerably higher per patient hospital charges than did non-diabetic patients. As shown in Table 12-9, diabetic patients generally had higher charges in all cost categories.

Differences by Status at the End of the Data Collection Period--

Earlier we observed that patients who had functioning grafts at the end of a particular follow-up data collection period had significantly lower hospital charges than patients who either died or experienced a graft failure during the follow-up period. Table 12-10 presents an itemized breakdown of the hospital charges for these two groups. Not surprisingly, charges in each cost category were substantially lower for patients who had functioning grafts

Table 12-9
Itemized Breakdown of Follow-up Hospital Charges by Primary Renal Diagnosis

	Time Period											
	Discharge to		3-6 Months		8-9 Months		9-12 Months		12-15 Months			
	3 Months	Posttransplant	Nondiabetes	Diabetes	Nondiabetes	Diabetes	Nondiabetes	Diabetes	Nondiabetes	Diabetes		
Medical/Surgical/Central Supplies	\$ 117	\$ 151	\$ 288	\$ 211	\$ 35	\$ 334	\$ 49	\$ 133	\$ 118	\$ 87		
Operating Room and Anesthesia	156	180	107	428	171	534	92	169	260	97		
Pharmacy	837	1,235	528	899	218	766	252	853	402	350		
Laboratory Tests	1,424	1,496	1,033	1,804	334	1,343	514	950	590	670		
Radiology/Nuclear Medicine	416	383	259	508	84	431	132	274	281	157		
Other Diagnostic Tests	72	87	76	81	42	128	16	76	56	84		
Blood Administration	89	35	42	161	4	43	2	28	103	16		
Oxygen and Gas Mixtures	0	6	0	0	0	0	0	0	3	0		
Physical, Vocational and Respiratory Therapy	133	47	213	238	24	140	3	101	48	157		
Dialysis	255	232	89	118	28	407	53	0	163	0		
Room and Board	1,978	1,873	1,185	1,736	461	1,902	635	1,384	967	979		
Other	63	73	15	16	24	46	11	56	30	114		
Total Per Patient Charges*	\$ 5,540	\$ 5,798	\$ 3,811	\$ 6,200	\$ 1,423	\$ 6,076	\$ 1,759	\$ 4,024	\$ 3,023	\$ 2,711		

*Hospital charges, excluding professional fees.

Table 12-10
Itemized Breakdown of Follow-up Hospital Charges by Status
at the End of the Follow-up Data Collection Period

	Time Period									
	Discharge to		3-6 Months		6-9 Months		9-12 Months		12-15 Months	
	3 Months Posttransplant	3 Months Posttransplant	Posttransplant	Posttransplant	Posttransplant	Posttransplant	Posttransplant	Posttransplant	Posttransplant	Posttransplant
	Functioning Graft	Failed Graft	Functioning Graft	Failed Graft	Functioning Graft	Failed Graft	Functioning Graft	Failed Graft	Functioning Graft	Failed Graft
Medical/Surgical/Central Supplies	\$ 76	\$ 836	\$ 62	\$ 5,553	\$ 72	\$ 2,403	\$ 69	\$ 101	\$ 55	\$ 1,583
Operating Room and Anesthesia	98	1,087	90	2,777	83	10,595	101	1,411	175	1,763
Pharmacy	759	3,602	359	7,546	289	6,099	394	983	151	6,621
Laboratory Tests	1,035	7,297	676	15,816	420	11,334	564	9,047	470	4,042
Radiology/Nuclear Medicine	284	2,173	184	4,044	101	4,312	155	1,739	153	3,059
Other Diagnostic Tests	53	404	39	1,147	42	1,355	30	75	48	504
Blood Administration	19	669	11	1,690	3	616	6	227	16	1,071
Oxygen and Gas Mixtures	4	0	0	0	3	0	0	0	2	0
Physical, Vocational and Respiratory Therapy	38	1,116	41	4,769	33	1,294	26	0	47	720
Dialysis	38	3,229	14	2,052	0	6,776	0	5,746	0	3,419
Room and Board	1,376	10,215	612	14,850	581	16,262	785	5,695	588	11,300
Other	57	217	11	121	21	554	19	176	29	604
Total Per Patient Charges*	\$ 3,635	\$ 31,049	\$ 2,299	\$ 60,365	\$ 1,626	\$ 61,600	\$ 2,151	\$ 25,200	\$ 1,734	\$ 35,986

*Hospital charges, excluding professional fees.

at the end of the follow-up period (that is, patients with "successful" grafts). Many of these charges, such as lower charges for room and board, reflect the fact that these patients spent fewer nights hospitalized than patients who experienced unfavorable outcomes during the period. For those patients who did not have functioning grafts at the end of the follow-up period, higher charges for other services (e.g., pharmacy, laboratory tests, dialysis) are most likely related to the treatment of rejection episodes.

Comparisons with National Data

Relatively little detailed national data are available on hospital charges and Medicare reimbursements for kidney transplantation. The data that are available have been reported primarily by Dr. Paul Eggers of the Health Care Financing Administration in individual published papers (Eggers, 1984:31; 1988:223) or in HCFA's Annual Report to Congress (HCFA, 1987; 1988) on the End-Stage Renal Disease Program. Some of these data have already been summarized (verbatim) in Chapter 1 of this report. In this section of the report we will review the available data on charges, estimated reimbursements, and average length of stay for transplant and nontransplant hospital stays. Table 12-11 presents a summary of 1986 transplant procedure charges, excluding professional fees, for all Medicare kidney transplant patients. Average total charges were \$34,247, of which \$34,054 were covered charges. An itemized breakdown of these charges is also provided in Table 12-11. Total room and board (including ICU/CCU) charges averaged \$6,425. Charges for pharmacy and laboratory charges averaged \$4,056 and \$4,949, respectively. Other charges included: \$2,853 for operating room, \$1,355 for radiology, \$1,216 for medical supplies, \$519 for anesthesia, and \$12,681 for

Table 12-11
1986 Medicare Kidney Transplants
Summary of Charges*

<u>Category</u>	<u>Amount</u>
Total Charges	\$34,247
Covered Charges	\$34,054
Accommodation	\$ 5,113
ICU/CCU	1,312
Ancillary	\$27,629
Operating Room	2,853
Pharmacy	4,056
Laboratory	4,949
Radiology	1,355
Medical Supplies	1,216
Anesthesia	519
Other (including kidney acquisition)	12,681
Medicare Reimbursement (including passthroughs)	\$31,474

Total Days (including ICU/CCU)	19.1
ICU/CCU days	2.2

*Charges, excluding professional fees

Source: Eggers, Health Care Financing Administration, 1989.

other expenses (a category that included kidney acquisition charges). The average Medicare reimbursement (including passthroughs) was \$31,474.

As already noted, Medicare reimbursements are not equal to hospital charges. Applying the national ratio of Medicare reimbursements to charges gives an estimate of the costs to Medicare for ESRD hospitalization. In 1982 and 1983, the cost to charges ratios were .672 and .649, respectively. In other words, in 1982 Medicare paid hospitals an average of 67.2 percent of charges in 1982 and 64.9 percent of charges in 1983.

In Table 12-12 we have summarized the available data on charges, estimated reimbursements, and average length of stay for transplant and nontransplant hospital stays for 1982 and 1983. The data upon which this table is based were taken from the 1982 and 1983 Medicare Provider Analysis and Review File (MEDPAR), which represents a 20 percent sample of hospital stays. The sample of stays includes procedure coding so it is possible to determine average charges and length of stay for transplant and nontransplant stays. Both the 1982 and 1983 MEDPAR contained shortfalls (about 1.0%) at the time of analysis. Thus, the figures were adjusted upward to approximate costs for 100 percent of stays. Hospital covered charges were estimated directly from the MEDPAR records.

As shown in Table 12-12, the average overall charge per stay for the ESRD population in 1982 was \$6,786 and in 1983, \$7,584. The average transplant stay had a charge of \$30,705 in 1982 and \$33,693 in 1983. The average charge for all nontransplant stays was \$5,550 in 1982 and \$6,212 in 1983. Of the total ancillary stays in 1982, the average for surgical stays was \$8,655. In 1983, the comparable figure was \$9,268. The estimated Medicare reimbursements per stay, based on the previously cited Medicare

Table 12-12
Charges, Estimated Reimbursements, and Average Length of Stay for
Transplant and Nontransplant Hospital Stays: 1982, 1983

Characteristic	All Stays	Transplant Stays	Nontransplant Stays	
			All	Non- Surgical
Number of Stays				
1982	100,051	4,917	95,134	57,030
1983	112,502	5,616	106,886	59,158
Charges (In Thousands)				
1982	\$678,946	\$150,976	\$572,970	\$198,181
1983	853,215	189,220	663,995	221,648
Charges Per Stay				
1982	\$6,786	\$30,705	\$5,550	\$3,475
1983	7,584	33,693	6,212	3,747
Estimated Reimbursement				
1982	\$456,252	\$101,456	\$354,796	\$133,177
1983	\$553,737	\$122,804	\$430,933	\$143,850
Estimated Reimbursement Per Stay				
1982	\$ 4,560	\$ 20,634	\$ 3,729	\$ 2,335
1983	4,922	21,867	4,032	2,432
Covered Days				
1982	1,092,034	140,626	951,408	497,972
1983	1,210,234	151,070	1,059,164	515,059
Average Length of Stay (ALOS)				
1982	10.9	28.6	10.0	8.7
1983	10.8	26.9	9.9	8.7

SOURCE: HCFA. 1987: 1988

cost to charges ratios, were \$4,560 in 1982 for all discharges, and \$4,922 in 1983. Medicare reimbursements for transplants in 1982 were \$20,634 and, in 1983, \$21,867. Medicare reimbursements for all nontransplant stays in 1982 were \$3,729 and, in 1983, \$4,032. Finally, among nontransplant stays in 1982, nonsurgical stays averaged \$2,335, while surgical stays average \$5,816. The comparable figures for 1983 were \$2,432 for nonsurgical stays and \$6,015 for surgical stays.

The foregoing data provide some perspective on the average transplant charges reported for our study. Recall that the average transplant procedure charge in our study was \$41,046 for the initial transplant stay (including approximately \$6,800 for professional fees). In 1986, total charges (excluding professional fees) for all Medicare transplant procedures was \$34,247. We do not have Medicare reimbursement data for our study patients. Also, the data on nontransplant hospital stays reported by HCFA are not directly comparable with our data because we did not distinguish among individual hospital stays. In other words, we did not calculate hospital charges on a per stay basis.

Finally, the national data available on transplant patients according to outcome (i.e., successful versus failed graft) are very scanty and quite dated. The available data for 1979 are summarized in Table 12-13. As shown, in 1979, Medicare reimbursements for a functioning kidney transplant were \$29,860, compared with \$42,432 for a failed graft. Clearly as our data show, failed grafts and deaths following transplantation can be very expensive.

Discussion

In this chapter we examined expenditures associated with renal transplantation through an analysis of the hospital charges associated with

Table 12-13
Average Per Capita Medicare Reimbursement Amounts for End-Stage
Renal Disease Transplant Patients, by Patient Outcome: 1979

<u>Patient Outcome</u>	<u>Reimbursement Per Person Year</u>
All transplants	\$34,914
First year:	
Graft functioning	29,860
Graft failed	42,432
Death	60,679
2nd year and over:	
Graft failed	30,189
2nd and 3rd year:	
Graft functioning	4,074

SOURCE: Eggers, 1984:37

transplant surgery and the charges of subsequent hospital stays during the first 15 months posttransplant. Data for our analysis were obtained from the hospital billing records maintained by the transplant center. Differences in hospital charges were examined separately for patients in the two initial immunosuppressive protocol groups (AZA + PRED + ALG versus CSA + PRED), and for patients grouped by primary renal diagnosis (diabetes versus non-diabetes). In addition, in examining transplant procedure charges, as well as hospital charges during the various follow-up data collection periods, we compared the hospital charges of patients with functioning grafts with patients who died and/or experienced a graft failure during the period. Also, using very limited data, we made some comparisons with national expenditures for renal transplantation services.

We observed tremendous variation in the total transplant procedure charges of the 396 patients included in the study. Transplant procedure charges ranged from a minimum of \$18,483.97 to a maximum of \$727,391.75. The mean transplant procedure charge was \$41,045.82. The tremendous variation in transplant procedure charges, of course, reflects differences in the length of the hospital stay. Of the 396 transplant procedures performed, the length of stay ranged from 6 to 252 days. However, other factors, besides length of stay, also influenced transplant procedure charges.

Although there was little difference in the average lengths of their hospital stays, patients who initially received CSA + PRED had considerably higher transplant procedure charges than patients who initially received AZA + PRED + ALG. Total transplant procedure charges at those centers that initially administer AZA + PRED + ALG averaged approximately \$10,000 less

than the transplant procedure charges at those centers that initially administer CSA + PRED. Moreover, patients who initially received CSA + PRED had considerably higher follow-up hospital charges than patients who initially received AZA + PRED + ALG, especially in the first six months following transplant surgery. During the first year following transplantation, the per patient hospital charges (excluding professional fees) for the CSA + PRED patient group (\$23,744) were over twice the per patient hospital charges for the AZA + PRED + ALG group (\$10,263).

There was little difference in average transplant procedure charges of diabetic and nondiabetic patients, or in the cost of subsequent hospitalizations in the first three months following transplantation. However, during the period between 3-months and 12-months posttransplant, diabetic patients were hospitalized more often than were nondiabetic patients. As a result, the per patient hospital charges (excluding professional fees) during the first year following transplantation averaged \$22,098 for diabetic patients, compared with an average of only \$12,533 for nondiabetic patients.

Not surprisingly, the major factor determining transplant procedure and follow-up hospital charges was the "success" or "failure" of the transplant procedure. The transplant procedure charges of patients who were discharged with functioning grafts were considerably lower than the charges of patients whose grafts were not successful. The 378 patients who were discharged from the hospital with functioning grafts were hospitalized an average 20.5 days and transplant procedure charges for this group averaged \$37,522. In contrast, 14 patients experienced a graft failure and four patients died during their initial hospital stay. These 18 patients were hospitalized, on average, 50.9 days and their hospital charges averaged \$115,949. Even when

this one extreme value was excluded from the calculations (a hospital bill of \$726,691 for a 252 day stay), the average transplant procedure charges of this group was approximately \$80,000.

The high costs associated with graft failure were also apparent in our analysis of hospital charges during the follow-up data collection period. Clearly, the most important factor underlying hospital charges during a particular follow-up data collection period was whether or not the patient experienced a graft failure and/or died during the period. A total of 24 patients experienced a graft failure or died during the period between initial hospital discharge and three months posttransplant. For these 24 patients, hospital charges (excluding professional fees) during this period averaged \$31,049 per patient. Of the 346 patients whose grafts were still functioning 3 months posttransplant, hospital charges during this same period averaged \$3,835 per patient. A similar pattern was observed during all follow-up data collection periods.

Renal transplantation is, without question, an expensive procedure. If successful, the average transplant procedure charges for the patients included in our study averaged approximately \$37,500, with follow-up hospital charges during the first year posttransplant averaging an additional \$10,000. Hospital charges for patients who experienced an unfavorable outcome (graft failure and/or death) were significantly higher. It should, of course, be emphasized that the figures presented in this chapter slightly underestimate total follow-up hospital charges, since they exclude professional fees. Moreover, some admissions to hospitals other than the center at which the transplant procedure was performed may not have been included in our analysis. Thus, the data reported here represent a conservative estimate of hospital

charges during the follow-up period. It is also important to remember that hospital charges are not the only costs incurred by patients following transplantation surgery. Other major costs associated with patient follow-up care include physician visits, routine laboratory tests, and outpatient medications (including immunosuppressive drugs). The cost of outpatient immunosuppressive drugs will be examined in the next chapter of this report.

CHAPTER 13

THE COST OF IMMUNOSUPPRESSION AND COVERAGE OF IMMUNOSUPPRESSIVE DRUGS FOR KIDNEY TRANSPLANT RECIPIENTS UNDER THE MEDICARE CATASTROPHIC COVERAGE ACT

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Introduction

In June, 1988, Congress took an historical step when it passed what may be Medicare's largest expansion in 23 years. The Medicare Catastrophic Coverage Act will shield the program's 32 million elderly and disabled beneficiaries from excessive hospital, doctor, and outpatient prescription drug bills and will extend Medicaid coverage for the poor. The final bill is totally self-financing (Sorian and Firshein, 1988:4).

The new benefits, when fully phased in, will help an estimated 8.0 million persons who incur catastrophic expenses for their health needs. It is expected that the costs associated with the Act will reach \$33.0 billion over five years. Not surprisingly, Medicare-eligible transplant recipients will benefit from various features of the Act. Most significant, perhaps, is the coverage made available for immunosuppressive drugs.

At this time the Health Care Financing Administration (HCFA) lacks the data and analyses required to estimate the implications of the drug benefits packages available under the Medicare Catastrophic Coverage Act. Such data are critical if HCFA is to stay abreast of likely developments in the field of transplant immunosuppression, and the possible costs associated with existing pharmacological agents, as well as those that are likely to emerge in the next several years. For example, since 1983, two major immunosuppressive agents have been approved by the Food and Drug Administration (FDA). These include cyclosporine (SANDIMMUNE) and OKT-3 (ORTHOCLONE) (Evans and Manninen, 1988:49; White, 1982; Macek, 1983:449; Kolata, 1983:40; Flechner, 1983:263; Goldstein, 1988:1; Ortho Multicenter Transplant Study Group, 1985:337; Belzer, 1988:3). Both drugs are expensive and have added to the direct costs associated with transplantation, although the indirect benefits

patients have derived partially offset these added direct costs (Krakauer, 1985; Task Force on Organ Transplantation, 1985; Evans and Manninen, 1987:1472).

The intent of this chapter is to provide the Office of the Actuary of the Health Care Financing Administration with the information, some of which was provided in Chapter 3, it requires to quantify the economic consequences of the Medicare Catastrophic Coverage Act (i.e., Medicare Part C coverage) for Medicare-eligible kidney transplant recipients. More specifically, the objectives of this chapter are as follows:

- To develop projections of the number of kidney transplant recipients that are likely to be eligible for Medicare Part C coverage through 1995. These estimates will be developed according to source of graft (i.e., living-related versus cadaveric donor), given various assumptions about the level of overall transplant activity--base case, modest increase, and substantial increase.
- To estimate per patient annual expenditures for both inpatient and outpatient immunosuppressive drugs during the first year of transplant and for all subsequent years. Estimates will be developed for various immunosuppressive protocols currently in use, including conventional immunosuppressive therapy as well as several variations of cyclosporine therapy (e.g., double-drug, triple-drug, and quadruple-drug therapy).
- To briefly highlight future developments in the field of transplant immunosuppression (e.g., prophylactic use of the monoclonal antibody OKT-3 (ORTHOCLONE), FK506, cyclosporine-G, and deoxyspergualin) that are likely to have economic implications of relevance to the Medicare program.

Taken together, the foregoing information can be used to calculate total Medicare program expenditures associated with transplant immunosuppression.

It is noteworthy that the analysis undertaken here does not constitute a cost-effectiveness analysis per se. In other words, no attempt is being made to identify which of several immunosuppressive protocols confers the greatest benefits on patients at the least cost. For example, it is possible that some readers anticipate an analysis that demonstrates whether or not the

more expensive immunosuppressive protocols provide added benefits, thus offsetting their greater expense. To reiterate, this is not the intent of this analysis.

Background

With FDA approval of cyclosporine in November 1983, the direct economic costs of organ transplantation increased considerably (Evans and Manninen, 1988:49). At the time the drug was approved, per patient annual costs were projected to be approximately \$5,000. This was considerably higher than the annual costs of approximately \$1,000 associated with what has become known as conventional immunosuppressive therapy consisting of azathioprine and prednisone (Evans and Manninen, 1988:49; Manninen and Evans, 1987:269). Within a very short period of time, it became evident that many transplant recipients were unable to afford cyclosporine therapy (i.e., cyclosporine and prednisone) (Task Force on Organ Transplantation, 1985). This was not surprising, given that in the National Kidney Dialysis and Kidney Transplantation Study (NKDKTS) it was estimated that nearly 36 percent of kidney transplant recipients had a family labor income below the poverty level (Evans et al., 1987). In the same study, it was found that over 40 percent of kidney transplant recipients received Social Security benefits, the majority, of course, due to disability. In a more recent analysis, Eggers estimates that about 50 percent of transplant recipients continue to receive Medicare benefits, even after a successful transplant (Eggers, 1988:223). Again, disability, not age, is the criterion upon which patients qualify.

Coverage of immunosuppressive drugs has not been devoid of attention. Over the past five or six years there have been Congressional hearings on the matter on several occasions (Evans, 1986:425). The National Task Force on Organ Transplantation prepared a detailed report entitled Report to the Secretary on Immunosuppressive Therapies, which contained a major recommendation as to the implementation of coverage for transplant recipients (Task Force on Organ Transplantation, 1985). Next, a stopgap measure was passed by Congress to assist patients with the payment of immunosuppressive drugs for the first-year posttransplant. Finally, the Medicare Catastrophic Coverage Act was passed. The Act will assist transplant recipients with immunosuppressive drug expenses after the first year of transplantation.

Each of the foregoing is important from the perspective of understanding the evolution of health care policy as it related to the Medicare-covered transplant recipient population. The scope of these initiatives, however, is determined by Medicare-eligibility, a nontrivial matter in and of itself. Currently, Medicare coverage is available for the majority (over 90%) of patients who receive kidney transplants (Eggers, 1988).

To underscore the importance of Medicare coverage of immunosuppressive drugs, as well as other prescription drugs, the key historical events/developments alluded to above will be summarily reviewed. This will be accomplished according to the temporal order in which they occurred.

Congressional Hearings

Beginning on April 13, 1983, Congress initiated its efforts to impart a greater understanding of what might be called the "transplant dilemma" (Evans, 1986:425). On that date a hearing was held, by then Congressman Albert R. Gore, Jr., that focused on the need for pediatric liver donors. Subsequent hearings were held by Congressman Gore on April 14, 1983 and April 27, 1983. Additional hearings were held on July 29, 1983, October 17, 1983, October 20, 1983, October 31, 1983, November 7, 1983, November 14, 1983, and February 9, 1984. The November 14, 1983 hearing, convened by Congressman Henry Waxman, before the Health and Environmental Subcommittee of the House of Representatives, specifically addressed the issue of payment for outpatient immunosuppressive drugs for transplant recipients.

At the November 14, 1983 hearing, Dr. Ronald M. Ferguson of the Ohio State University presented data from the University of Minnesota (where Dr. Ferguson trained) concerning the costs and benefits of cyclosporine as an immunosuppressant. Dr. Ferguson noted that, although cyclosporine was likely to be a costly drug, it reduced patient morbidity and decreased the length of hospital stays for transplant recipients. The evidence he provided was persuasive and well-received by the Committee members who attended the hearing. However, rather than propose an approach to resolve the difficult issue of coverage for immunosuppressive drugs, Congress eventually directed the National Task Force on Organ Transplantation to review the problem and to offer recommendations (see Appendix G).

The National Task Force on Organ Transplantation

When the National Organ Transplantation Act became law (Public Law 98-507) on October 19, 1984, coverage of immunosuppressive drugs was accorded primary importance among the tasks, the as yet to be appointed National Task Force on Organ Transplantation would address (see Appendix G). The Task Force was to report within seven months on the safety, effectiveness, and costs of immunosuppressive drugs, the extent of insurance reimbursement, problems patients encountered in obtaining drugs, and mechanisms that might be employed to assure that individuals needing the drugs could obtain them. The Task Force was established in January, 1985 and a report on immunosuppressive therapies was submitted to the Secretary of Health and Human Services on October 21, 1985 (Task Force on Organ Transplantation, 1985). Dr. Henry Krakauer (1985) of the Health Care Financing Administration performed extensive analyses that were incorporated directly into the Task Force Report. Dr. Roger W. Evans developed projections of the program expenditures likely to be associated with both conventional and cyclosporine therapy for renal transplant recipients (Task Force on Organ Transplantation, 1985).

The Task Force was unanimous in agreeing upon several points in developing its recommendations to assure patient access to immunosuppressive drugs (Task Force on Organ Transplantation, 1985). These were as follows (quoted directly):

- Any approach to resolving the problem of patient access to immunosuppressive drugs should address immunosuppressants in general, not only cyclosporine.
- The problems associated with access to immunosuppressive therapies and the cost thereof are generic to all transplant recipients, not just renal transplant recipients.

- Any approach to resolving the financial dilemma within which many transplant recipients have been placed must be targeted to those patients who are regarded as most needy financially.

The Task Force concluded that cyclosporine constituted a major breakthrough in transplant immunosuppression--it increased patient and graft survival rates, decreased hospital stays, and was associated with fewer episodes of infection and rejection than conventional immunosuppressive therapy. In short, mortality and morbidity were significantly reduced with cyclosporine.

The Task Force found that cyclosporine was cost-beneficial (Task Force on Organ Transplantation, 1985). Although the cost of the drug was higher than conventional therapy, because of a reduced rate of complications and shorter hospital stays, cyclosporine favorably impacted upon total expenditures associated with transplantation.

Finally, the Task Force determined that approximately 25 percent of the transplant patient population had no private insurance for immunosuppressive medications and lacked coverage by a State Medicaid program or other State program (Task Force on Organ Transplantation, 1985; Intergovernmental Health Policy Project, 1985). These transplant recipients experienced serious difficulty in obtaining and paying for needed immunosuppressive drugs, especially cyclosporine. Some patients were forced to change drug protocols, and some kidney transplant recipients reportedly lost their grafts as a result (Task Force on Organ Transplantation, 1985). The Task Force also found that there was evidence that inability to pay for immunosuppressive medications had been a factor in the initial selection of patients for transplantation.

Based on its findings, the Task Force recommended "... the establishment of a joint Health Care Financing Administration--Public Health Service program to provide immunosuppressive medications to transplant centers for distribution to financially needy Medicare-eligible transplant patients" (Task Force on Organ Transplantation, 1985). The program was to be administered by the Public Health Service and supported with Medicare Trust Funds. It is noteworthy that the Task Force concluded that "... any Federal funding for immunosuppressive medications should be limited to assisting only financially needy Medicare-eligible patients."

Subsequent Legislation

While the recommendations of the Task Force were believed to have merit, there were various problems associated with their implementation. Nonetheless, Congress felt the need to provide some form of assistance to Medicare-eligible transplant recipients. Therefore, in Section 9335(c) of Public Law 99-509, Congress amended Section 1861(s)(2) of the Act to provide Medicare coverage of immunosuppressive drugs, furnished to an individual who received an organ transplant for which Medicare payment was made, within one year after the date of the transplant procedure. Coverage of these drugs was available under Medicare Part B for immunosuppressive drugs furnished on or after January 1, 1987. To implement the new amendment, HCFA issued manual instructions to its Medicare contractors in April, 1987.

On January 19, 1988, HCFA published a proposed rule change in the Federal Register (see Appendix H). HCFA proposes to change the statutory phrase "within one year after the date of the transplant procedure" to mean 365

days from the date on which the inpatient is discharged from the hospital. This change is intended to eliminate the possibility of overlap between Part A and Part B coverage, since the patient is generally hospitalized many days after the transplant procedure, per se. HCFA notes that "If we were to provide Part B benefits beginning at the time of operation, we would have to adjust the DRG weights to exclude the costs of postoperative immunosuppressive drugs."

In addition to the above, HCFA is proposing to provide coverage for those immunosuppressive drugs that have been specifically labeled as such and are approved by the FDA. Also, HCFA would provide coverage for other drugs that are used in conjunction with immunosuppressive drugs as part of the therapeutic regimen reflected in FDA approved labeling for immunosuppressive drugs. By December, 1986, the FDA had identified and approved for marketing only four specifically labeled immunosuppressive drugs to prevent rejection of a transplanted organ or tissue. They are: cyclosporine, azathioprine, ATGAM (antithymocyte globulin), and OKT-3 (ORTHOCLONE).

At the present time, steroids (i.e., prednisone) are not included as a covered item. However, HCFA plans on including coverage for this drug under the condition that "... other drugs which are used in conjunction with immunosuppressives but not themselves labeled as immunosuppressive drugs include, for example, adrenal corticosteroid (prednisone) administered to patients receiving cyclosporine in accordance with FDA labeling of cyclosporine."

The proposed rule changes described above have not yet been finalized. Comments regarding these changes were due to HCFA no later than March 21, 1988.

The Medicare Catastrophic Coverage Act

We have briefly commented upon the Medicare Catastrophic Coverage Act above. Two provisions of the Medicare Catastrophic Coverage Act are of particular interest to Medicare-eligible transplant recipients. The first of these has to do with prescription drugs, and the second with home intravenous and immunosuppressive drugs. Below, each of these provisions is highlighted.

Prescription drug coverage will be phased in over three years. In 1991, Medicare will pay 50 percent above a \$600 drug deductible; in 1992, Medicare will cover 60 percent above a limit; and in 1993 and thereafter, Medicare would cover 80 percent of the costs over a limit. The limit is to be set to ensure that 16.8 percent of beneficiaries are always covered. The Department of Health and Human Services could freeze coverage at 60 percent in 1993 and 1994, provided there are cost overruns.

Immunosuppressive drug coverage has been expanded. Beginning in 1990, Medicare will pay 80 percent of the costs of home intravenous and immunosuppressive drugs used after the first year of transplantation. The first year drug costs will continue to be covered under Public Law 99-509 described above.

The details of these coverages are yet to be worked out, however, it is evident that the transplant recipient population will impact significantly upon the Medicare Catastrophic Coverage Act. As indicated above, immunosuppressive drugs are expensive, but equally important, although not always recognized, is the size of the expenditures associated with nonimmunosuppressive prescription drugs required by transplant recipients. Many transplant recipients develop complications secondary to their primary

end-stage disease. For example, hypertension, gastric ulcers, and bone disorders are common among long-term survivors of transplantation (Washer et al., 1983:49; Opelz et al., 1977:27; Murray et al., 1976:565; Blohme and Brynager, 1985:23; Birkeland, 1983:504; Margules et al., 1972:735; Kirkman et al., 1982:347; Abele et al., 1982:264; Simmons et al., 1977:234; Starzl et al., 1974:606; Woodruff et al., 1976:85; Vanrenterghem et al., 1987:3762; Toussaint et al., 1987:3760; Rao, 1987:3758; Le Francois et al., 1987:3767). Therefore, the total outpatient drug expenditures associated with the transplant recipient population are likely to be considerable.

Discussion

A clear need exists for an analysis that will enable HCFA to fully appreciate and quantify both the policy and economic implications the Medicare Catastrophic Coverage Act will have for transplant recipients, as well as the Medicare program. Developments have occurred within organ transplantation with great rapidity. Cyclosporine, perhaps, represents the most significant development in the past decade of transplantation. Other developments are on the horizon. For example, at least two new immunosuppressive agents appear to hold some promise. These are, FK506--a fermentation product isolated from Streptomyces Tsukubaensis that has been shown to be immunosuppressive both in vitro and in rats--and 15 deoxyspergualin (DSG)--a 15-deoxy analogue of the antitumor antibiotic spergualin (DSG) (Starzl et al., 1987:1; Ochiai et al., 1988:209; Todo et al., 1988:215; Zeevi et al., 1988:220; Amemiya et al., 1988:229; Todo et al., 233; Engemann et al., 1988:237). Also, existing agents are being used in a manner different from which they were intended. For example, OKT-3

(ORTHOCLONE) was originally intended to be used to treat acute rejection and is now being used prophylactically (Goldstein, 1988:1; Burke *et al.*, 1988:252; Ackermann *et al.*, 1988:242; Shield *et al.*, 1988:190; Weimar *et al.*, 1988:96). Finally, various immunosuppressive protocols are being applied using a wide variety of agents, some of which exclude cyclosporine either temporarily or permanently. These are often referred to as multiple drug protocols administered simultaneously or sequentially (Lund, 1987; Hall *et al.*, 1988:1499; First *et al.*, 1986:132; Fries *et al.*, 1988:130; Deierhoi *et al.*, 1987:71; 1987:1917; Broyer *et al.*, 1987:3582; Slapak, 1987:958). The economic implications of these protocols vary considerably. For example, if cyclosporine is dropped from the maintenance protocol of patients at 3-, 6-, 9-, or 12-months posttransplant, as was predicted by the National Task Force on Organ Transplantation, the cost of immunosuppression decreases considerably (Lund *et al.*, 1983:2857; Lennard *et al.*, 1987:3594; Keown, 1987:1; Hoitsma *et al.*, 1987:584; Henrikson *et al.*, 1986:1002; Hoitsma *et al.*, 1987:584; Gonwa *et al.*, 1987:225; Flechner *et al.*, 1985:276; Shapira *et al.*, 1986:1261). Alternatively, if cyclosporine is continued indefinitely, or if OKT-3 is used prophylactically, the cost of immunosuppression increases considerably. The implications of these developments must be factored into projections concerning the Medicare Catastrophic Coverage Act.

Materials and Methods

This section of the chapter provides an abbreviated review of transplant immunosuppression and describes the data used in our analyses. This information, some of which was provided in Chapter 3, is essential to understanding the results presented here.

Immunosuppressive Drugs and Protocols

Transplant immunosuppression is very complicated in practice, although in principle the goal it is intended to achieve is straightforward. Immunosuppression is required to enable the patient to retain the transplanted kidney. The goal is to keep the "host" from identifying the "foreign" tissue. Unfortunately, if the patient is over-immunosuppressed, they may retain the graft (the kidney), but become highly susceptible to a variety of infections--viral, bacterial, fungal, protozoan, and nocardial. In short, while the purpose of immunosuppression is to prevent rejection, its untoward outcome is often infection. Ideally, the goal is to sufficiently immunosuppress the patient, while eliminating, or at least minimizing, the risk of infection. It is generally believed that the more specific the immunosuppressive agent, the greater the likelihood that this therapeutic goal can be achieved. Thus far, the immunosuppressive properties of even the most effective of immunosuppressive agents--cyclosporine--are too general. It is hoped that further syntheses of cyclosporine will produce an analogue that is increasingly specific (e.g. Cyclosporine-G).

A wide range of pharmacological agents are available to induce immunological tolerance. The drugs most commonly used today include azathioprine, prednisone, and cyclosporine. In addition, two polyclonal antibodies and one monoclonal antibody have been incorporated into the immunosuppressive regimens of some transplant teams. The polyclonal antibodies are: (1) antithymocyte globulin (ATGAM) produced by Upjohn and (2) antilymphocyte globulin (ALG) produced in laboratories at the University of Minnesota under the direction of Dr. Richard M. Condie. While ATGAM is commercially produced and approved by the Food and Drug Administration

(FDA), Minnesota ALG (MALG) is yet to be approved by the FDA, although the agent is widely available and its benefits well-recognized. Throughout this chapter the acronyms ALG, MALG, and ATG are used interchangeably.

The only monoclonal antibody available commercially for purposes of transplant is OKT-3 which goes under the product name ORTHOCLONE and is produced by Ortho Pharmaceuticals. While ORTHOCLONE is primarily used to treat rejection episodes, ALG and ATG are used both prophylactically and to treat rejection. Recently many transplant programs have begun to use ORTHOCLONE prophylactically.

The other immunosuppressive agents mentioned above--prednisone, azathioprine and cyclosporine--are all produced commercially and have been approved by the FDA. Prednisone is a corticosteroid, and for many years has played a key role in transplant immunosuppression, and is produced generically. Azathioprine was first synthesized in 1961 and has also been a stable component of the immunosuppressive armamentarium. The product name for azathioprine is IMURAN and it is produced by Burroughs Welcome. Finally, cyclosporine is perhaps the most significant breakthrough in transplant immunosuppression. Cyclosporine is produced by Sandoz Pharmaceuticals and goes by the product name SANDIMMUNE.

Transplant immunosuppression is accomplished by following protocols that combine various agents according to a variety of administration schedules. Each immunosuppressive protocol can be divided into two phases--induction and maintenance. The drugs administered during each phase may differ from team to team, although it is possible to delineate several protocols that are in use today. This is accomplished in Table 13-1.

Table 13-1

Drugs Used in Various Kidney Transplant Immunosuppressive Drug Protocols

Drug Protocol	Protocol Phase	
	Induction	Maintenance
Conventional Immunosuppression		
Without Antithymocyte Globulin	PRED + AZA	PRED + AZA
With Antithymocyte Globulin	PRED + AZA + ALG	PRED + AZA
Double Drug Cyclosporine Therapy	CSA + PRED	CSA + PRED
Triple-Drug Cyclosporine Therapy		
U.S. Variation	PRED + AZA + ALG	CSA + PRED
European Variation	CSA + PRED + AZA	CSA + PRED + AZA
Prophylactic OKT-3 Variation	PRED + AZA + OKT-3	CSA + PRED + AZA
Quadruple-Drug Cyclosporine Therapy	CSA + PRED + AZA + ALG	CSA + PRED + AZA

Explanation:

PRED = prednisone
 AZA = azathioprine
 ALG = antilymphocyte or antithymocyte globulin (polyclonal antibody)
 CSA = cyclosporine
 OKT-3 = Orthoclone (monoclonal antibody)

As indicated, there are four major types of protocols in use today. They are as follows:

- Conventional immunosuppression.
- Double-drug cyclosporine therapy.
- Triple-drug cyclosporine therapy.
- Quadruple-drug cyclosporine therapy.

In addition, there are several variations of different major protocols. In Table 13-1 we have distinguished among the various protocols based on the number of drugs used during the induction protocol phase (with the exception of conventional therapy).

In general, conventional immunosuppressive therapy is only used by patients transplanted during the precyclosporine era (before November, 1983), or by patients unable to tolerate cyclosporine. Following FDA approval of cyclosporine, there was almost a wholesale shift towards the use of cyclosporine in the United States. Today, nearly all patients are placed on cyclosporine, while very few patients who have been on conventional therapy are converted to cyclosporine, unless unique problems arise.

From time to time there have been discussions concerning the possible conversion of cyclosporine patients to conventional therapy in an effort to minimize side-effects and to reduce the total expenditures associated with immunosuppression. Cyclosporine is an expensive drug in comparison to azathropine and prednisone. In fact, in deriving the initial estimates of the costs associated with cyclosporine, the National Task Force on Organ Transplantation assumed that conversion from cyclosporine to conventional therapy would occur within one year. However, the conversion experience has been unsatisfactory and patients are remaining on cyclosporine, even

though they have had trouble paying for the drug. For the time being, therefore, it is unwise to assume that conversion will become an accepted practice in the near term.

As stated above, the drugs administered to transplant recipients vary according to phase. Induction treatment refers to the initial use of immunosuppressive agents during the immediate, posttransplantation period of about six weeks. It is during this period that the patient's status is most uncertain. Graft function may be unstable, there is almost always coexistent renal injury, and the immune system is in a state of increased alloreactivity. Maintenance treatment is initiated after graft function has stabilized, when both kidney and liver function are normal or subnormal. Infectious complications are absent and alloreactivity has decreased steadily. The maintenance period is often separated into two time frames--before and after six months posttransplantation.

After Land (1987), several figures have been prepared to illustrate various approaches to the immunosuppressive therapy of transplant recipients. These approaches have been described in detail elsewhere and will not be discussed at length here.

Figure 13-1 shows single, double and triple drug maintenance therapy. Each protocol involves the use of cyclosporine, although it is noteworthy that single drug therapy is used in England and other locations worldwide, but not in the United States. As indicated, some patients may start with triple-drug therapy but later be placed on double-drug therapy.

Figure 13-2 provides examples of induction treatment using triple drug therapy. The administration of agents can be described as follows:

Figure 13-1: Maintenance Treatment: Examples of Different Protocols Using Cyclosporine (CSA) Alone or in Combination with Prednisone (PRED) and/or Azathioprine (AZA)

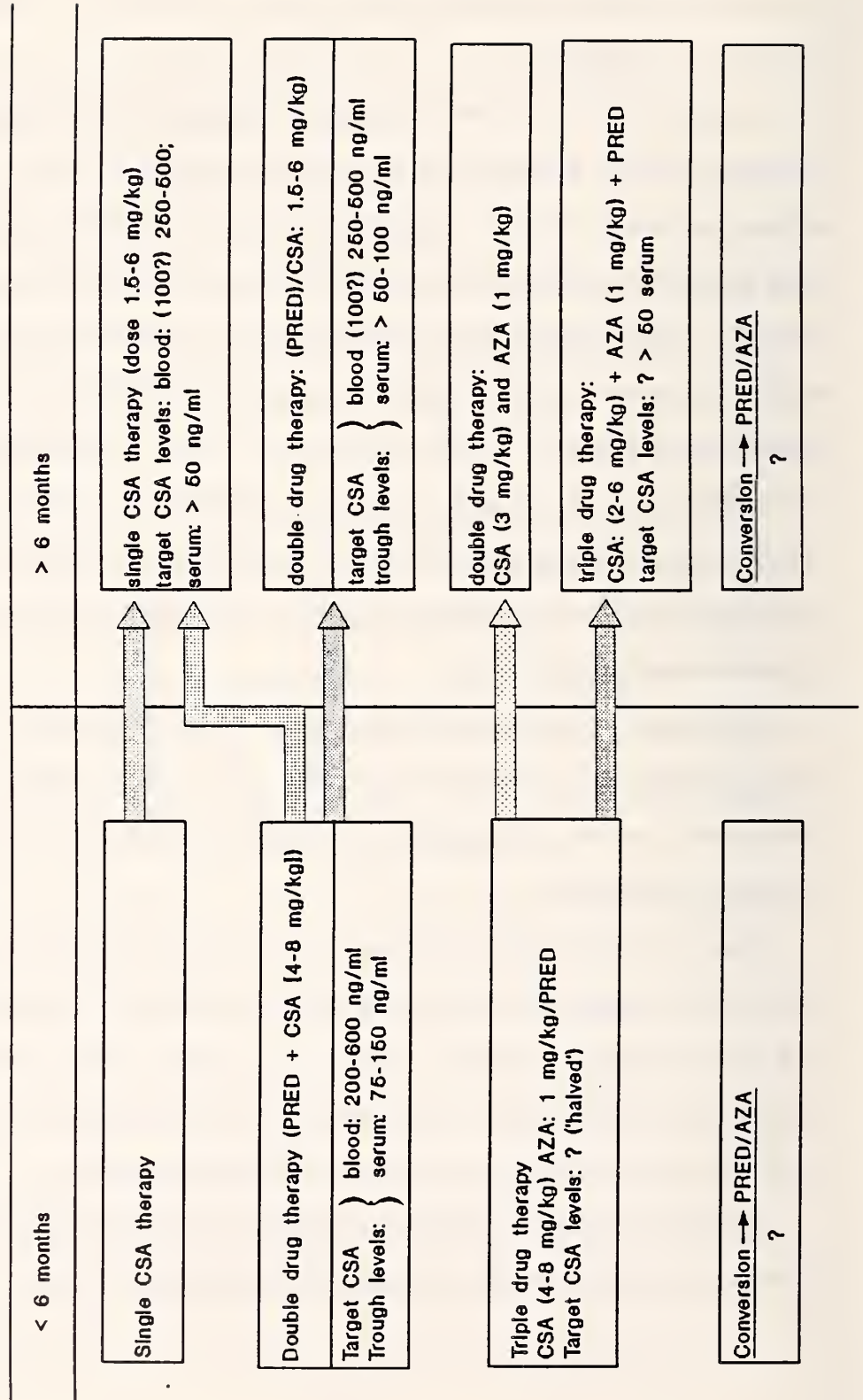
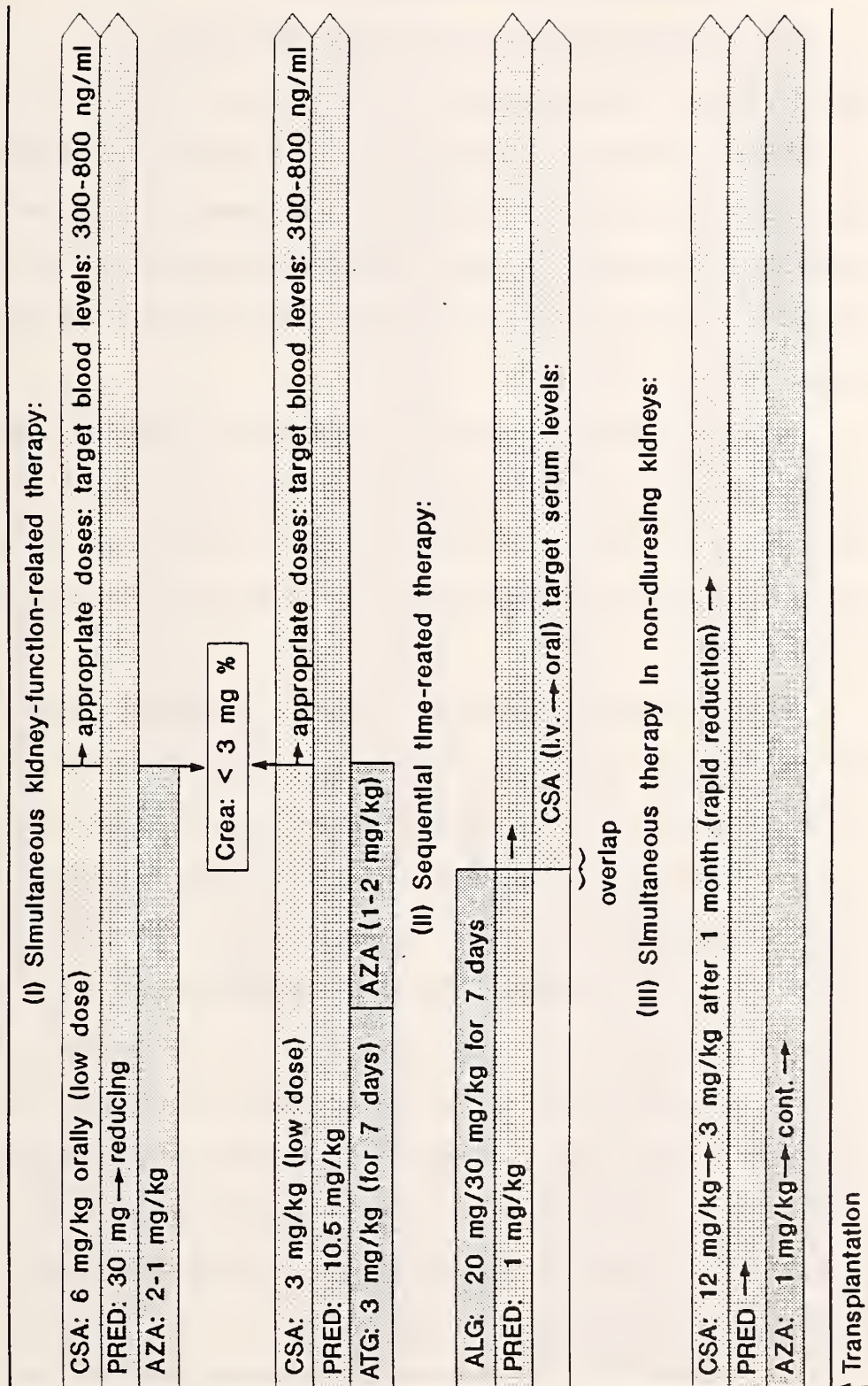


Figure 13-2: Induction Treatment: Examples of Triple-Drug Therapy Using Combinations of Cyclosporine (CSA), Prednisone (PRED), Azathioprine (AZA), and ALG and ATG



- (1) Simultaneous kidney-function-related therapy.
- (2) Sequential time-related therapy, and
- (3) Simultaneous therapy in non-diuresing kidneys.

Clearly, as shown, the drugs used vary according to the type of therapy offered.

Figure 13-3 provides a number of options for quadruple-drug therapy during the induction phase of treatment. Again, there are variations on this form of therapy--sequential kidney-function-related therapy and simultaneous (nonfunction-related) therapy. As indicated, ALG or ATG is incorporated into each of these protocols.

Figure 13-4 indicates the options available for maintenance treatment using cyclosporine alone or in combination with prednisone and/or azathioprine. Once again, cyclosporine monotherapy has never been practiced in the United States and should, therefore, be omitted from consideration in cost projections.

Finally, Figure 13-5 identifies all the various protocols available for both the induction and maintenance phases of the transplant experience. As indicated, variations are numerous, and confusion is easily engendered when each of the protocols is considered. While not all of these protocols are in use in the United States it is particularly difficult to state with absolute certainty how many patients in the United States are on each of the various protocols. This is an important consideration in projecting costs, since the costs associated with the various drugs vary according to the transplant protocol being used. While it is possible to develop the estimated costs of each protocol per patient, it is more complicated to determine the number of patients on conventional therapy, as well as those on each of the various forms of cyclosporine therapy.

Figure 13-3: Induction Treatment: Examples of Quadruple-Drug Therapy Using Combinations of Cyclosporine (CSA), Prednisone (PRED), Azathioprine (AZA), and ALG and ATG

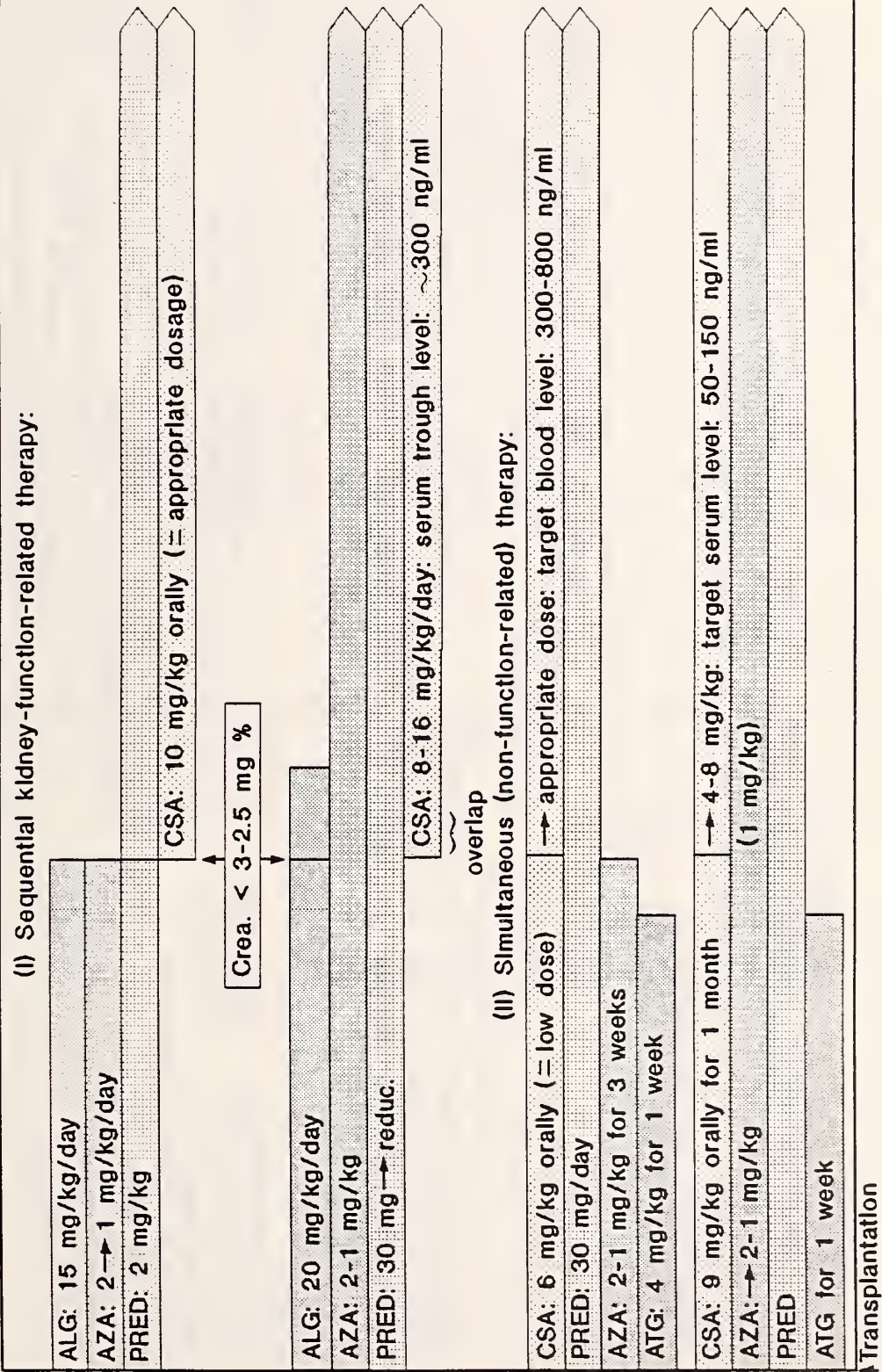


Figure 13-4: Maintenance Treatment: Examples of Different Protocols Using Cyclosporine (CSA) Alone or in Combination with Prednisone (PRED) and/or Azathioprine (AZA)

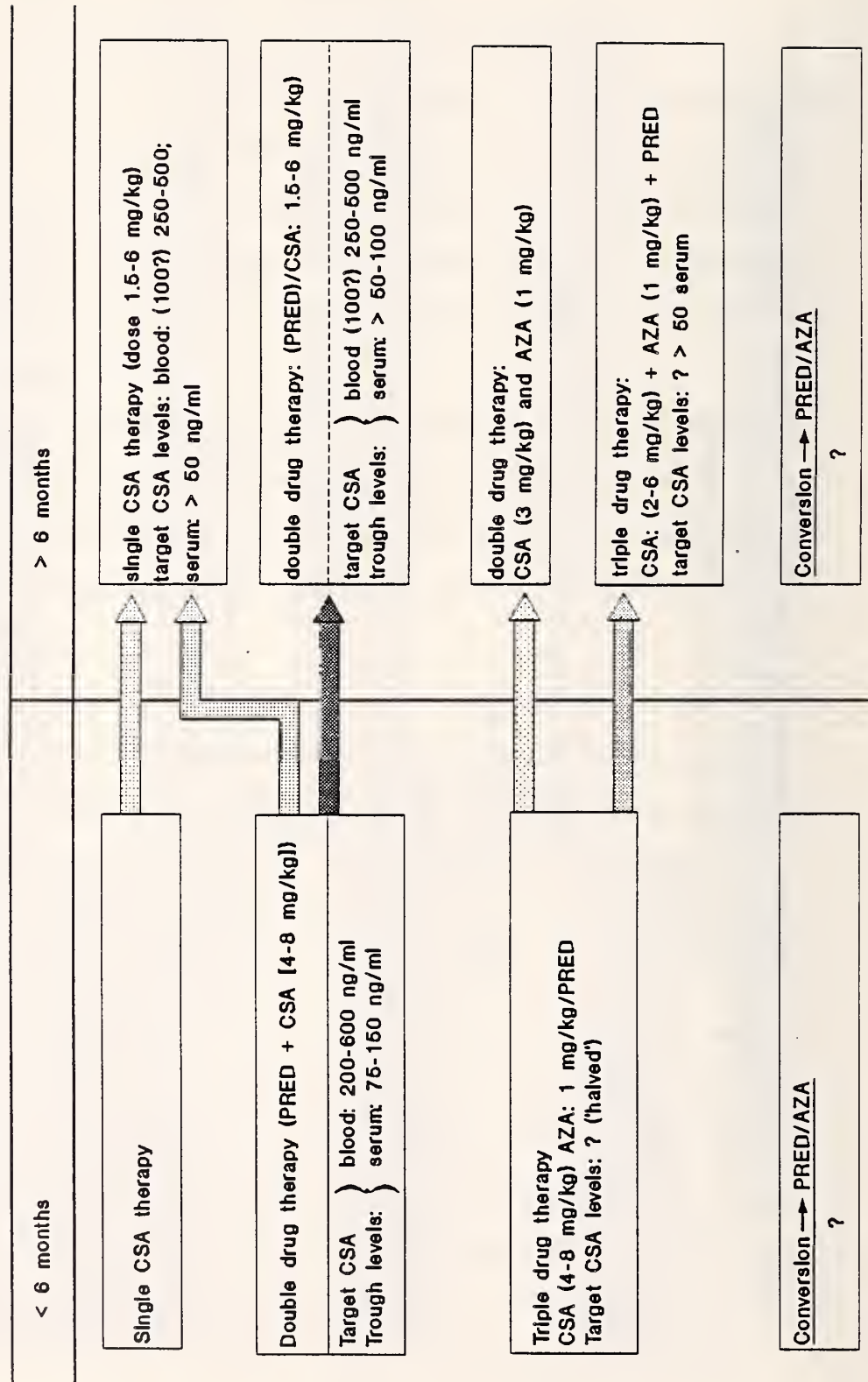
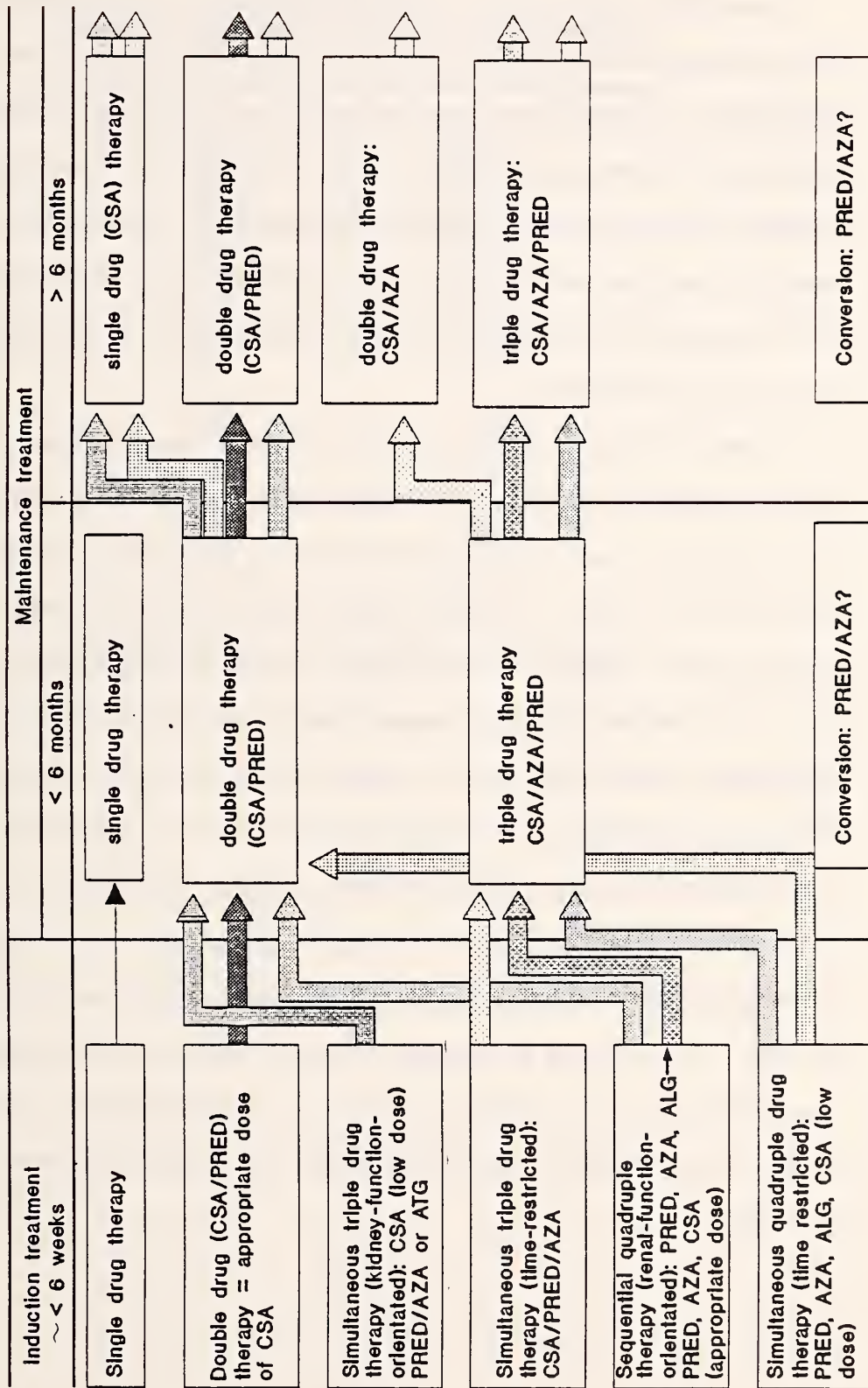


Figure 13-5: Examples of Clinical Use of Cyclosporine (CSA) in Renal Transplantation With Prednisone (PRED), Azathioprine (AZA), Antilymphocyte Globulin (ALG) and Antithymocyte Globulin (ATG)



Estimates of the Level of Annual Transplant Activity

Since 1980 there has been a substantial increase in the overall level of kidney transplant activity, although year-to-year variations have been considerable for both living-related as well as cadaveric kidney transplants. Somewhat disconcertingly, however, there was virtually no increase in transplant activity between 1986 and 1987, despite the fact that numerous attempts were being made to improve the overall supply of donors. Table 13-2 indicates the approximate number of kidney donors in the United States for the period 1980-1987.

Research indicates that the potential supply of cadaveric kidney donors greatly exceeds the actual supply. While each living related donor provides one kidney for transplant, each cadaveric donor contributes two kidneys. Estimates of the supply of cadaveric donor kidneys range between 17,000 and 57,500 annually, subject to donor selection criteria and willingness to consent for organ donation. This would suggest that the number of transplants performed annually could greatly increase over the 8,967 performed in 1987. However, there are many factors that may contribute to the stabilization, or even a decline, in the availability of donor kidneys. As outlined by Manninen and Evans (1985:3111), these factors include: (1) seat belt laws (2) laws requiring the use of child restraint seats (3) better trauma care (4) drunk driving laws and (5) the 55-mph speed limit. In addition, since human immunodeficiency virus (HIV) positivity is a contraindication to organ donation, there could be a substantial decrease in organ supply over the next five years.

Table 13-2

Number of Cadaveric Kidney Donors by Year

<u>Year</u>	<u>Number</u>
1980	2,138
1981	2,142
1982	2,300
1983	2,705
1984	3,290
1985	3,637
1986	3,990
1987	4,000

Given the foregoing, we have chosen to provide several different estimates of the likely level of transplant activity for the period 1988-1995. These are hereafter referred to as:

- Base case estimates.
- Modest increase estimates.
- Substantial increase estimates.

The base case estimates assume that the level of increase in transplant activity between 1988 and 1995 will be identical to what it was in 1987. In other words, there will be no increase in cadaveric transplants and a 1.0 percent increase in living-related donor transplants. A complete summary of the base case estimates is provided in Table 13-3.

Assuming there is a possibility of some increase in transplant activity, we have generated a set of modest increase estimates. In this instance, the percent increase for the period 1988-1995 is based on the average annual increase for the period of 1984-1987, 1984 being the year cyclosporine was introduced on a large scale in the United States. The modest increase estimates are summarized in Table 13-4.

Finally, although it is unlikely, we have derived still a third set of estimates, hereafter referred to as substantial increase estimates. These estimates assume a three-percent increase in living-related donor kidney transplants. Although unrealistic, these estimates assume that the supply of donor kidneys increases substantially but also, and perhaps most importantly, that the number of people requiring transplants would increase markedly. With 13,000 people currently on the waiting list for a kidney transplant, it is unlikely that in excess of 42,000 people will require a transplant in 1995. The substantial increase estimates are summarized in Table 13-5.

Table 13-3

Actual (1980-1987) and Projected (1988-1995)
Kidney Transplants: Base Case

<u>Year</u>	<u>Living Related Donor</u>		<u>Cadaveric Donor</u>	
	<u>Number</u>	<u>Percent Increase</u>	<u>Number</u>	<u>Percent Increase</u>
1980	1,275	7.5	3,422	14.0
1981	1,458	14.6	3,425	0.0
1982	1,677	15.0	3,691	7.8
1983	1,784	6.4	4,328	17.3
1984	1,704	-4.5	5,264	20.9
1985	1,876	10.1	5,819	10.5
1986	1,887	1.0	7,089	21.8
1987	1,907	1.0	7,060	0.0

1988	1,926	1.0	7,060	0.0
1989	1,945	1.0	7,060	0.0
1990	1,964	1.0	7,060	0.0
1991	1,984	1.0	7,060	0.0
1992	2,004	1.0	7,060	0.0
1993	2,024	1.0	7,060	0.0
1994	2,044	1.0	7,060	0.0
1995	2,064	1.0	7,060	0.0

Table 13-4

Actual (1980-1987) and Projected (1988-1995)
Kidney Transplants: Modest Increase

<u>Year</u>	<u>Living Related Donor</u>		<u>Cadaveric Donor</u>	
	<u>Number</u>	<u>Percent Increase</u>	<u>Number</u>	<u>Percent Increase</u>
1980	1,275	7.5	3,422	14.0
1981	1,458	14.6	3,425	0.0
1982	1,677	15.0	3,691	7.8
1983	1,784	6.4	4,328	17.3
1984	1,704	-4.5	5,264	20.9
1985	1,876	10.1	5,819	10.5
1986	1,887	1.0	7,089	21.8
1987	1,907	1.0	7,060	0.0
<hr style="border-top: 1px dashed black;"/>				
1988	1,935	1.45	7,999	13.3
1989	1,963	1.45	9,063	13.3
1990	1,991	1.45	10,268	13.3
1991	2,020	1.45	11,634	13.3
1992	2,049	1.45	13,181	13.3
1993	2,079	1.45	14,934	13.3
1994	2,109	1.45	16,920	13.3
1995	2,140	1.45	19,170	13.3

NOTE: Percent increase for period 1988-1995 based on average annual increase for the period 1984-1987.

Table 13-5

Actual (1980-1987) and Projected (1988-1995)
Kidney Transplants: Substantial Increase

<u>Living Related Donor</u>			<u>Cadaveric Donor</u>	
<u>Year</u>	<u>Number</u>	<u>Percent Increase</u>	<u>Number</u>	<u>Percent Increase</u>
1980	1,275	7.5	3,422	14.0
1981	1,458	14.6	3,425	0.0
1982	1,677	15.0	3,691	7.8
1983	1,784	6.4	4,328	17.3
1984	1,704	-4.5	5,264	20.9
1985	1,876	10.1	5,819	10.5
1986	1,887	1.0	7,089	21.8
1987	1,907	1.0	7,060	0.0

1988	1,964	3.0	8,472	25.0
1989	2,023	3.0	11,031	25.0
1990	2,084	3.0	13,789	25.0
1991	2,147	3.0	17,236	25.0
1992	2,211	3.0	21,545	25.0
1993	2,277	3.0	26,931	25.0
1994	2,345	3.0	33,664	25.0
1995	2,415	3.0	42,080	25.0

The foregoing estimates are used throughout the report to provide a sufficiently broad perspective so as to increase the sensitivity of the analysis required by the HCFA actuaries. Of these estimates, both the base case and the modest increase estimates are considered to be most valid. However, given the numerous attempts that are being made to improve the supply of organ donors, it is hard to imagine that there will not be year-to-year increases over the next five years.

Graft Survival Rates

In order to project the total number of living kidney transplant recipients for the period 1988 to 1995, various assumptions must be made as to the graft survival rates of kidney transplant recipients. Unlike extrarenal transplant procedures, a distinction is made between patient and graft survival rates for kidney transplant recipients. A patient may lose his or her graft, not die, and return to maintenance dialysis. While patient survival rates are an important consideration, within the context of this report they have little meaning. Instead, graft survival rates are the key to projecting the number of patients that may benefit from the Medicare Part C Program for immunosuppressive drug coverage.

We have prepared two tables to summarize the overall graft survival rates used in projecting the size of the kidney transplant patient population. One-year survival rates for both living-related and cadaveric kidney transplants are summarized in Table 13-6. As shown, patients who receive living-related donor transplants have a higher survival rate than do patients who have received cadaveric grafts. As is apparent in Tables 13-7 and 13-8,

Table 13-6

Kidney Transplant One-Year Graft Survival Rates, 1980-1995

<u>Year</u>	<u>One-Year Graft Survival Rates</u>	
	<u>Living Related Donor</u>	<u>Cadaveric Donor</u>
1980	85	61
1981	85	63
1982	85	62
1983	86	63
1984	88	70
1985	88	74
1986	90	74
1987	90	74

1988	90	75
1989	90	75
1990	91	75
1991	91	76
1992	91	76
1993	92	77
1994	92	77
1995	93	78

SOURCE: 1980-1984 see Eggers, 1988:223.

Table 13-7
Living Related Donor Kidney Transplant Graft Survival Rates

<u>Year</u>	<u>Year Posttransplant</u>				
	<u>1 Year</u>	<u>2 Year</u>	<u>3 Year</u>	<u>4 Year</u>	<u>5 Year</u>
1980	85	83	81	79	77
1981	85	83	81	79	77
1982	85	83	81	79	77
1983	86	84	82	80	78
1984	88	86	84	82	80
1985	88	86	84	82	80
1986	88	86	84	82	80
1987	89	87	85	83	81

1988	89	87	85	83	81
1989	89	87	85	83	81
1990	90	88	86	84	82
1991	91	89	87	85	83
1992	92	90	88	86	84
1993	92	90	88	86	84
1994	93	91	89	87	85
1995	93	91	89	87	85

SOURCE: Revised based on Evans and Manninen, 1988:49.

Table 13-8
Cadaver Donor Kidney Transplant Graft Survival Rates

<u>Year</u>	<u>Year Posttransplant</u>				
	<u>1 Year</u>	<u>2 Year</u>	<u>3 Year</u>	<u>4 Year</u>	<u>5 Year</u>
1980	61	56	50	45	41
1981	63	61	55	50	46
1982	61	58	56	54	52
1983	62	59	57	55	53
1984	68	66	63	59	54
1985	71	70	65	60	55
1986	72	71	66	61	60
1987	73	72	67	62	61

1988	74	72	70	68	66
1989	75	73	71	69	67
1990	76	74	72	70	68
1991	77	75	73	71	69
1992	78	76	74	72	70
1993	80	78	76	74	72
1994	82	80	78	76	74
1995	84	82	80	78	76

SOURCE: Revised based on Evans and Manninen, 1988:49.

these differences, according to source of graft, persist during the first few years of transplant.

It is noteworthy that the estimates provided in Tables 13-6, 13-7, and 13-8 are national averages, some centers have higher graft survival rates, while the results of others may be much poorer.

Obviously patients survive beyond five-years. To deal with the problem we determined appropriate attrition rates for all years posttransplant. This was accomplished using published data provided by Dr. Paul Terasaki in his annual summary on the status of kidney transplantation (Terasaki, 1985; 1986; 1987). These estimates are somewhat difficult to derive based on the fact that patients are on a wide range of immunosuppressive protocols, and the true long-term outcome of the various approaches may be unclear when patients are aggregated without concern for immunosuppressive protocol. In the absence of data to the contrary, we have derived a reasonable set of estimates given current experience and knowledge. Therefore, after five years, we have assumed a graft failure rate of four percent annually for both living-related and cadaveric kidney transplants for the years 1980 through 1995.

Discussion

The estimates which follow are based on the foregoing data. We have attempted to build into our estimates a level of sensitivity that will suitably meet the needs of HCFA. It is obviously difficult to factor in every possible development that may occur over the period 1988-1995. New developments in immunosuppression, for example, may significantly alter graft survival, while a decrease in organ donor supply would greatly alter the numbers of patients

with functioning grafts. For this reason, we have provided three sets of estimates--base case, modest increase, and substantial increase.

Results

This section of the chapter is divided into several subsections, in which we will examine the number of living transplant recipients by source of graft, and then by immunosuppressive protocol. Next, we will separate the patients into two groups--the Medicare-eligible and those ineligible for Medicare because their grafts have continued to be successful at the end of three-years.

Because drug costs vary according to year posttransplant, we have divided all the estimates into several categories. These are: first year, second year, third year, fourth year, fifth year, and six years and over. In reality, after the first year of transplant, most patients will have relatively stable immunosuppressive drug needs, and therefore, costs. Nonetheless, we have chosen to separate patients according to year posttransplant.

Number of Living Kidney Transplant Recipients

The estimates which follow have been divided into several categories--living- related donor, cadaveric donor, and totals. While the totals may be of greatest interest, we have separated the living-related donor transplants from the cadaveric to provide perspective. The number of patients who continue to live with a successful transplant continues to grow, largely as a function of increased transplant volume and improved patient survival. Eventually, the long-term consequences of transplantation and chronic immunosuppression

will have to be dealt with. Both morbidity and complication rates may increase as a function of longevity.

Living-Related Donor--

Three estimates of the number of living kidney transplant recipients with living-related donor grafts are provided in Tables 13-9, 13-10, and 13-11. For the period 1979 through 1987 the estimates are the same. Projections are offered for the years 1988 through 1995. As is apparent from these tables, there are only minor differences in the estimates due to the very small increase in the number of living-related donor kidney transplants that are likely during the aforementioned period.

It is noteworthy that as cadaveric kidney transplantation has become increasingly successful, there is considerable debate within the renal transplant community concerning the merits of living-related donor kidney transplantation. Since organ donation constitutes a risk to the living-related donor, there are those who suggest that the procedure should be discontinued. For example, the University of Pittsburgh does very few living-related donor kidney transplants. The proponents of living-related donor transplantation counter, however, by pointing out that there is an acute need for donor kidneys and the adverse consequences of living-related donor kidney donation are minimal. While the foregoing debate is unresolved, it is unlikely that living-related kidney transplantation will be abandoned unless, or until, the supply of cadaveric kidneys increases.

Table 13-9

Base Case Estimates: Number of Living Kidney Transplant
Recipients with Living Related Donor Grafts
by Year, 1979-1995

<u>Year</u>	<u>First Year</u>	<u>Second Year</u>	<u>Third Year</u>	<u>Fourth Year</u>	<u>Fifth Year</u>	<u>Sixth Year +</u>	<u>Total</u>
1979	973	891	1047	829	876	3005	7620
1980	1084	937	856	1032	855	3970	8733
1981	1239	1020	866	797	972	4072	8966
1982	1425	1152	956	842	785	5077	10238
1983	1534	1358	1108	918	806	5533	11258
1984	1500	1481	1308	1064	880	5943	12176
1985	1651	1431	1409	1241	1021	6394	13147
1986	1698	1595	1346	1320	1174	6784	13917
1987	1716	1623	1501	1278	1267	7438	14823
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1988	1733	1659	1510	1407	1210	7946	15464
1989	1751	1676	1545	1434	1351	8539	16294
1990	1787	1712	1560	1449	1359	9000	16867
1991	1805	1748	1595	1483	1392	9644	17667
1992	1844	1786	1610	1498	1406	10016	18160
1993	1862	1804	1647	1532	1439	10520	18803
1994	1901	1842	1663	1548	1453	10928	19335
1995	1920	1860	1700	1583	1488	11506	20057

Table 13-10

Modest Increase Estimates: Number of Living Kidney Transplant
Recipients with Living Related Donor Grafts
by Year, 1979-1995

<u>Year</u>	<u>First Year</u>	<u>Second Year</u>	<u>Third Year</u>	<u>Fourth Year</u>	<u>Fifth Year</u>	<u>Sixth Year +</u>	<u>Total</u>
1979	973	891	1047	829	876	3005	7620
1980	1084	937	856	1032	855	3970	8733
1981	1239	1020	866	797	972	4072	8966
1982	1425	1152	956	842	785	5077	10238
1983	1534	1358	1108	918	806	5533	11258
1984	1500	1481	1308	1064	880	5943	12176
1985	1651	1431	1409	1241	1021	6394	13147
1986	1698	1595	1346	1320	1174	6784	13917
1987	1716	1623	1501	1278	1267	7438	14823
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1988	1742	1659	1510	1407	1210	7946	15473
1989	1767	1683	1545	1434	1351	8539	16318
1990	1812	1727	1567	1449	1359	9048	16962
1991	1838	1772	1610	1490	1392	9850	17952
1992	1885	1818	1633	1512	1413	10016	18276
1993	1913	1844	1677	1553	1453	10526	18965
1994	1961	1892	1701	1576	1473	10946	19549
1995	1990	1919	1746	1619	1515	11543	20333

Table 13-11

Substantial Increase Estimates: Number of Living Kidney Transplant
Recipients with Living Related Donor Grafts
by Year, 1979-1995

<u>Year</u>	<u>First Year</u>	<u>Second Year</u>	<u>Third Year</u>	<u>Fourth Year</u>	<u>Fifth Year</u>	<u>Sixth Year +</u>	<u>Total</u>
1979	973	891	1047	829	876	3005	7620
1980	1084	937	856	1032	855	3970	8733
1981	1239	1020	866	797	972	4072	8966
1982	1425	1152	956	842	785	5077	10238
1983	1534	1358	1108	918	806	5533	11258
1984	1500	1481	1308	1064	880	5943	12176
1985	1651	1431	1409	1241	1021	6394	13147
1986	1698	1595	1346	1320	1174	6784	13917
1987	1716	1623	1501	1278	1267	7438	14823
1988	1768	1659	1510	1407	1210	7946	15499
1989	1821	1709	1545	1434	1351	8539	16397
1990	1896	1780	1591	1449	1359	9000	17076
1991	1954	1855	1659	1512	1392	9214	17586
1992	2034	1932	1709	1558	1434	9383	18050
1993	2095	1990	1782	1626	1497	9692	18681
1994	2181	2072	1835	1675	1542	10625	19930
1995	2246	2134	1913	1747	1610	11716	21366

Cadaveric Donor--

Base case, modest increase, and substantial increase estimates of the number of cadaveric kidney transplant recipients have been provided in Tables 13-12, 13-13, and 13-14. Once again, the estimates for the period 1979 through 1987 are identical, however, as shown, the total number of living cadaveric kidney transplant recipients differs markedly based upon the estimates of interest. In 1990, for example, the base case estimate is 32,407, the modest increase estimate is 36,777, and the substantial increase estimate is 41,069. By 1995, the estimates increase to 43,852, 74,555, and 123,287. Clearly, total Medicare program expenditures will vary widely depending upon these estimates.

Total Number of Patients--

Since the quantities of immunosuppressive drugs administered vary minimally between living-related donor and cadaveric donor kidney transplant recipients, both patient groups have been combined according to type of estimate in Tables 13-15, 13-16, and 13-17. Because of the wide variation in the number of cadaveric transplant recipients according to type of estimate, there is considerable variation in the total number of living-related kidney transplant recipients. In 1990, the totals are as follows: 49,274 (base), 53,739 (modest) and 58,145 (substantial). By 1995 the comparable estimates are 63,910 (base), 94,888 (modest) and 144,653 (substantial).

Table 13-12

Base Case Estimates: Number of Living Kidney Transplant
 Recipients with Cadaveric Donor Grafts
 by Year, 1979-1995

<u>Year</u>	<u>First Year</u>	<u>Second Year</u>	<u>Third Year</u>	<u>Fourth Year</u>	<u>Fifth Year</u>	<u>Sixth Year +</u>	<u>Total</u>
1979	1502	1250	945	729	642	1084	6152
1980	2087	1532	1250	970	795	2211	8845
1981	2158	1814	1411	1166	945	2663	10158
1982	2288	1850	1608	1291	1083	2890	11011
1983	2727	2030	1678	1506	1201	3355	12497
1984	3685	2683	2067	1713	1574	4421	16143
1985	4306	3474	2554	1956	1678	5260	19228
1986	5246	3899	3158	2337	1846	5844	22330
1987	5224	4750	3491	2843	2164	6291	24763
1988	5295	4801	4324	3200	2685	7086	27391
1989	5295	4802	4307	3899	2968	8034	29305
1990	5295	4871	4377	3954	3686	10223	32407
1991	5366	4942	4448	4024	3742	12919	35440
1992	5366	4942	4448	4024	3742	15056	37578
1993	5436	5013	4518	4095	3812	17383	40258
1994	5436	5013	4518	4095	3812	19027	41902
1995	5507	5083	4589	4165	3883	20625	43852

Table 13-13

Modest Increase Estimates: Number of Living Kidney Transplant
Recipients with Cadaveric Donor Grafts
by Year, 1979-1995

<u>Year</u>	<u>First Year</u>	<u>Second Year</u>	<u>Third Year</u>	<u>Fourth Year</u>	<u>Fifth Year</u>	<u>Sixth Year +</u>	<u>Total</u>
1979	1502	1250	945	729	642	1084	6152
1980	2087	1532	1250	970	795	2211	8845
1981	2158	1814	1411	1166	945	2663	10158
1982	2288	1850	1608	1291	1083	2890	11011
1983	2727	2030	1678	1506	1201	3355	12497
1984	3685	2683	2067	1713	1574	4421	16143
1985	4306	3474	2554	1956	1678	5260	19228
1986	5246	3899	3158	2337	1846	5844	22330
1987	5224	4750	3491	2843	2164	6291	24763
1988	5999	4801	4324	3200	2685	7086	28095
1989	6797	5439	4307	3899	2968	8034	31444
1990	7701	6253	4959	3954	3686	10223	36777
1991	8842	7188	5710	4559	3742	12919	42959
1992	10018	8144	6469	5166	4239	15056	49092
1993	11499	9359	7446	5955	4894	17853	57006
1994	13028	10603	8436	6748	5545	20461	64820
1995	14953	12182	9707	7777	6399	23538	74555

Table 13-14

Substantial Increase Estimates: Number of Living Kidney Transplant
Recipients with Cadaveric Donor Grafts
by Year, 1979-1995

<u>Year</u>	<u>First Year</u>	<u>Second Year</u>	<u>Third Year</u>	<u>Fourth Year</u>	<u>Fifth Year</u>	<u>Sixth Year +</u>	<u>Total</u>
1979	1502	1250	945	729	642	1084	6152
1980	2087	1532	1250	970	795	2211	8845
1981	2158	1814	1411	1166	945	2663	10158
1982	2288	1850	1608	1291	1083	2890	11011
1983	2727	2030	1678	1506	1201	3355	12497
1984	3685	2683	2067	1713	1574	4421	16143
1985	4306	3474	2554	1956	1678	5260	19228
1986	5246	3899	3158	2337	1846	5844	22330
1987	5224	4750	3491	2843	2164	6291	24763

1988	6354	4801	4324	3200	2685	7086	28450
1989	8273	5761	4307	3899	2968	8034	33242
1990	10342	7611	5253	3954	3686	10223	41069
1991	13099	9652	6950	4829	3742	12919	51191
1992	16374	12065	8687	6288	4490	15056	62961
1993	20737	15297	11031	7998	5957	18089	79109
1994	25921	19121	13789	9997	7446	21662	97936
1995	32822	24238	17505	12712	9480	26530	123287

Table 13-15

Base Case Estimates: Total Number of Living Kidney Transplant
Recipients by Year, 1979-1995

<u>Year</u>	<u>First Year</u>	<u>Second Year</u>	<u>Third Year</u>	<u>Fourth Year</u>	<u>Fifth Year</u>	<u>Sixth Year +</u>	<u>Total</u>
1979	2474	2140	1992	1558	1518	4089	13772
1980	3171	2468	2105	2002	1650	6181	17578
1981	3397	2834	2277	1963	1917	6736	19124
1982	3714	3001	2565	2133	1868	7967	21248
1983	4261	3388	2786	2424	2008	8888	23755
1984	5184	4164	3375	2777	2454	10364	28319
1985	5957	4906	3963	3197	2699	11654	32375
1986	6944	5493	4505	3657	3019	12628	36247
1987	6941	6372	4992	4121	3431	13729	39585

1988	7028	6460	5834	4607	3894	15031	42855
1989	7046	6478	5851	5333	4318	16573	45599
1990	7082	6583	5937	5403	5045	19224	49274
1991	7171	6690	6043	5507	5134	22562	53107
1992	7209	6728	6058	5522	5148	25073	55737
1993	7298	6816	6165	5627	5252	27903	59061
1994	7337	6854	6182	5642	5266	29955	61236
1995	7426	6943	6289	5749	5371	32131	63910

Table 13-16

Modest Increase: Total Number of Living Kidney
Transplant Recipients
by Year, 1979-1995

<u>Year</u>	<u>First Year</u>	<u>Second Year</u>	<u>Third Year</u>	<u>Fourth Year</u>	<u>Fifth Year</u>	<u>Sixth Year +</u>	<u>Total</u>
1979	2474	2140	1992	1558	1518	4089	13772
1980	3171	2468	2105	2002	1650	6181	17578
1981	3397	2834	2277	1963	1917	6736	19124
1982	3714	3001	2565	2133	1868	7967	21248
1983	4261	3388	2786	2424	2008	8888	23755
1984	5184	4164	3375	2777	2454	10364	28319
1985	5957	4906	3963	3197	2699	11654	32375
1986	6944	5493	4505	3657	3019	12628	36247
1987	6941	6372	4992	4121	3431	13729	39585

1988	7741	6460	5834	4607	3894	15031	43568
1989	8564	7123	5851	5333	4318	16573	47762
1990	9513	7981	6527	5403	5045	19271	53739
1991	10680	8960	7319	6049	5134	22768	60911
1992	11903	9962	8101	6677	5652	25073	67368
1993	13412	11203	9122	7508	6347	28379	75971
1994	14990	12495	10137	8323	7018	31407	84369
1995	16943	14102	11453	9396	7914	35081	94888

Table 13-17

Substantial Increase: Total Number of Living Kidney
Transplant Recipients by Year, 1979-1995

<u>Year</u>	<u>First Year</u>	<u>Second Year</u>	<u>Third Year</u>	<u>Fourth Year</u>	<u>Fifth Year</u>	<u>Sixth Year +</u>	<u>Total</u>
1979	2474	2140	1992	1558	1518	4089	13772
1980	3171	2468	2105	2002	1650	6181	17578
1981	3397	2834	2277	1963	1917	6736	19124
1982	3714	3001	2565	2133	1868	7967	21248
1983	4261	3388	2786	2424	2008	8888	23755
1984	5184	4164	3375	2777	2454	10364	28319
1985	5957	4906	3963	3197	2699	11654	32375
1986	6944	5493	4505	3657	3019	12628	36247
1987	6941	6372	4992	4121	3431	13729	39585
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1988	8122	6460	5834	4607	3894	15031	43949
1989	10094	7470	5851	5333	4318	16573	49639
1990	12238	9392	6843	5403	5045	19224	58145
1991	15053	11507	8608	6341	5134	22133	68777
1992	18408	13998	10396	7845	5924	24440	81011
1993	22832	17287	12813	9623	7454	27782	97790
1994	28102	21193	15624	11672	8988	32287	117866
1995	35068	26372	19418	14458	11090	38246	144653

Number of Living Kidney Transplant Recipients by Immunosuppressive Protocol

Because the costs of immunosuppressive drugs vary according to the patient's immunosuppressive protocol, it is important that we project the number of patients who are on the two major categories of immunosuppressive protocols--cyclosporine therapy and conventional therapy. Cyclosporine therapy is defined as any protocol that incorporates cyclosporine at some point in time.

It should be recalled that cyclosporine was approved by the FDA in November, 1983. The adoption of cyclosporine by renal transplant teams was gradual, however. Below, by year and type of transplant, we have indicated the actual (1983-1987) and projected (1988-1995) percentage of transplants performed that involved, or are projected to involve, cyclosporine as a primary immunosuppressive agent.

<u>Year</u>	<u>Living Related Donor</u>	<u>Cadaveric Donor</u>
1983	13%	18%
1984	34%	62%
1985	51%	78%
1986	58%	88%
1987	77%	92%
1988	85%	95%
1989	90%	95%
1990	95%	95%
1991	95%	95%
1992	95%	95%
1993	95%	95%
1994	95%	95%
1995	95%	95%

The data for the years 1983-1987 were provided by Dr. Paul Eggers of the Health Care Financing Administration.

Living-Related Donor--

Three sets of estimates as to the number of living kidney transplant recipients with living-related donor grafts according to immunosuppressive protocol are provided in Tables 13-18, 13-19, and 13-20. As shown, cyclosporine therapy was initiated in 1983. The estimates we provide are probably quite accurate, taking into consideration the diffusion of cyclosporine.

Cadaveric Donor--

Once again, separate sets of estimates have been derived for cadaveric donor kidney transplants. These are presented in Tables 13-21, 13-22, and 13-23 by immunosuppressive protocol and by year, for the period 1983-1995.

Total Number of Living Patients--

Finally, and perhaps most critically, we have merged the results of our separate analyses for living-related donor and cadaveric donor kidney transplant recipients. Estimates for the total kidney transplant patient population by immunosuppressive protocol, by year, are provided in Tables 13-24, 13-25, and 13-26.

Number of Medicare-Eligible Living Kidney Transplant Recipients

Perhaps the most critical estimates of the size of the transplant patient population are those which concern the Medicare-covered portion of the living patients. Elsewhere Eggers estimates that 50 percent of kidney transplant recipients continue to qualify for Medicare coverage after the third year with a successful graft. This, of course is the segment of the patient

Base Case Estimates: Number of Living Kidney Transplant Recipients With Living-Related Donor Grafts by Immunosuppressive Protocol by Year, 1983-1995

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Table 13-19
Modest Increase Estimates: Number of Living Kidney Transplant Recipients
With Living-Related Donor Grafts by Immunosuppressive Protocol
by Year, 1983-1995

Year	Cyclosporine Therapy						Conventional Therapy					
	1st	2nd	3rd	4th	5th	6th	1st	2nd	3rd	4th	5th	6th
	Year	Year	Year	Year	Year	Year	Year	Year	Year	Year	Year	Year
1983	184	0	0	0	0	0	1350	1358	1108	918	808	5533
1984	510	178	0	0	0	0	990	1303	1308	1064	880	5943
1985	842	487	169	0	0	0	809	945	1240	1241	1021	8394
1986	985	813	458	158	0	0	713	781	888	1182	1174	6784
1987	1322	941	765	435	152	0	395	882	735	843	1115	7438

1988	1480	1277	878	718	411	143	281	382	834	889	798	7802
1989	1590	1431	1189	832	889	531	177	253	355	682	662	8008
1990	1721	1555	1332	1116	788	1150	91	173	235	333	571	7898
1991	1746	1683	1449	1266	1072	1853	92	89	181	223	320	7997
1992	1791	1727	1551	1360	1201	2752	94	91	82	151	212	7284
1993	1817	1752	1593	1475	1307	3774	98	92	84	78	145	6752
1994	1863	1797	1616	1497	1400	4772	98	95	85	79	74	6174
1995	1891	1823	1659	1538	1439	5883	100	98	87	81	78	5660

Sub-Total							Sub-Total					
11258							11258					
12178							12178					
13147							13147					
13917							13917					
14823							14823					

1988	1480	1277	878	718	411	143	281	382	834	889	798	7802
1989	1590	1431	1189	832	889	531	177	253	355	682	662	8008
1990	1721	1555	1332	1116	788	1150	91	173	235	333	571	7898
1991	1746	1683	1449	1266	1072	1853	92	89	181	223	320	7997
1992	1791	1727	1551	1360	1201	2752	94	91	82	151	212	7284
1993	1817	1752	1593	1475	1307	3774	98	92	84	78	145	6752
1994	1863	1797	1616	1497	1400	4772	98	95	85	79	74	6174
1995	1891	1823	1659	1538	1439	5883	100	98	87	81	78	5660

Sub-Total							Sub-Total					
15473							15473					
16318							16318					
16962							16962					
17951							17951					
18276							18276					
18965							18965					
19549							19549					
20332							20332					

Table 13-20
Substantial Increase Estimates: Number of Living Kidney Transplant Recipients
With Living-Related Donor Grafts by Immunosuppressive Protocol
by Year, 1983-1995

Year	<u>Cyclosporine Therapy</u>						<u>Conventional Therapy</u>						Grand Total
	1st	2nd	3rd	4th	5th	6th	1st	2nd	3rd	4th	5th	6th	
	Year	Year	Year	Year	Year	Sub- Total	Year	Year	Year	Year	Year	Sub- Total	
1983	184	0	0	0	0	0 184	1350	1358	1108	918	806	5533	11258
1984	510	178	0	0	0	0 688	990	1303	1308	1064	880	5943	12176
1985	842	487	169	0	0	0 1498	809	945	1240	1241	1021	6394	13147
1986	985	813	458	158	0	0 2414	713	781	888	1162	1174	6784	13917
1987	1322	941	765	435	152	0 3615	395	662	735	843	1115	7438	14823
1988	1502	1277	876	718	411	143 4928	265	382	634	689	798	7802	15499
1989	1639	1452	1189	832	689	531 6332	182	256	355	602	662	8008	16397
1990	1802	1602	1352	1116	788	1150 7810	95	178	239	333	571	7851	17076
1991	1856	1762	1493	1285	1072	1853 9321	98	93	166	227	320	7362	17586
1992	1932	1836	1623	1402	1219	2752 10764	102	97	85	156	215	6631	18050
1993	1990	1890	1693	1544	1347	3619 12084	105	99	89	81	158	6073	18682
1994	2072	1968	1743	1591	1465	4826 13666	109	104	92	84	77	5799	19930
1995	2134	2027	1817	1659	1530	5998 15165	112	107	96	87	81	5670	21317

Table 13-21
Base Case Estimates: Number of Living Kidney Transplant Recipients
With Cadaveric Donor Grafts by Immunosuppressive Protocol
by Year, 1983-1995

Year	<u>Cyclosporine Therapy</u>						<u>Conventional Therapy</u>						Grand Total
	1st	2nd	3rd	4th	5th	6th	1st	2nd	3rd	4th	5th	6th	
	Year	Year	Year	Year	Year	Sub- Total	Year	Year	Year	Year	Year	Sub- Total	
1983	491	0	0	0	0	0 491	2236	2030	1678	1506	1201	3355	12497
1984	2285	483	0	0	0	0 2768	1400	2200	2067	1713	1574	4421	16143
1985	3359	2154	460	0	0	0 5972	947	1320	2094	1956	1676	5260	19228
1986	4616	3041	1956	421	0	0 10036	630	656	1200	1916	1646	5844	22330
1987	4806	4180	2723	1762	390	0 13861	418	570	766	1060	1774	6291	24763
<hr/>													
1988	5030	4417	3805	2496	1664	366 17779	265	364	519	704	1020	6720	27391
1989	5030	4562	3982	3431	2315	1669 21169	265	240	345	466	653	6165	30304
1990	5030	4628	4156	3637	3244	3926 24624	265	244	219	316	442	6297	32407
1991	5097	4695	4225	3823	3442	6726 28009	268	247	222	201	299	6193	35440
1992	5097	4695	4225	3623	3555	9315 30711	268	247	222	201	187	5741	37576
1993	5164	4762	4292	3690	3622	12030 33760	272	251	226	205	191	5354	40256
1994	5164	4762	4292	3690	3622	14262 35993	272	251	226	205	191	4765	41902
1995	5231	4829	4360	3957	3669	16641 38707	275	254	229	206	194	3984	43852

Table 13-22
Modest Increase Estimates: Number of Living Kidney Transplant Recipients With Cadaveric Donor Grafts by Immunosuppressive Protocol by Year, 1983-1995

<u>Cyclosporine Therapy</u>							<u>Conventional Therapy</u>								
Year	1st Year	2nd Year	3rd Year	4th Year	5th Year	6th Year+ Total	1st Year	2nd Year	3rd Year	4th Year	5th Year	6th Year+ Total	Grand Total		
1983	491	0	0	0	0	0	491	2236	2030	1678	1506	1201	3355	12006	12497
1984	2285	483	0	0	0	0	2768	1400	2200	2067	1713	1574	4421	13375	16143
1985	3359	2154	460	0	0	0	5972	947	1320	2094	1956	1678	5260	13256	19228
1986	4616	3041	1958	421	0	0	10036	630	858	1200	1916	1846	5844	12294	22330
1987	4806	4180	2723	1762	390	0	13861	418	570	768	1080	1774	6291	19302	24763
1988	5699	4417	3805	2496	1684	366	18448	300	384	519	704	1020	6720	9647	20895
1989	6457	5167	3962	3431	2315	1869	23202	340	272	345	468	653	6185	8242	31444
1990	7316	5941	4711	3637	3244	3928	28776	385	313	248	316	442	6297	8001	36777
1991	8400	6828	5424	4331	3442	6726	35152	442	359	285	228	299	6193	7807	42959
1992	9517	7737	6145	4908	4027	9315	41849	501	407	323	258	212	5741	7443	49092
1993	10924	8891	7073	5658	4649	12476	49671	575	468	372	298	245	5377	7335	57006
1994	12377	10073	8014	6410	5267	15624	57766	651	530	422	337	277	4837	7055	64821
1995	14205	11573	9222	7388	6079	19473	67940	748	609	485	389	320	4065	6615	74555

Table 13-23

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Table 13-24
Base Case Estimates: Total Number of Living Kidney
Transplant Recipients by Immunosuppressive Protocol by Year, 1983-1985

Year	Cyclosporine Therapy						Conventional Therapy						Grand Total
	1st	2nd	3rd	4th	5th	6th	1st	2nd	3rd	4th	5th	6th	
	Year	Year	Year	Year	Year	Sub- Total	Year	Year	Year	Year	Year	Sub- Total	
1983	675	0	0	0	0	0	3586	3388	2786	2424	2008	8888	23755
1984	2794	681	0	0	0	0	2390	3503	3375	2777	2454	10384	28318
1985	4201	2841	629	0	0	0	1756	2265	3334	3197	2699	11654	32375
1986	5601	3854	2416	579	0	0	1343	1639	2089	3078	3019	12628	38248
1987	8128	5121	3489	2197	542	0	813	1252	1504	1924	2889	13729	39585
<hr/>													
1988	6504	5694	4681	3214	2076	510	525	766	1153	1394	1819	14522	42855
1989	6806	5986	5151	4263	3004	2400	440	491	700	1070	1315	14173	45599
1990	6728	6168	5484	4753	4032	5076	354	415	453	650	1013	14148	49274
1991	6812	6355	5661	5084	4514	8578	359	334	382	424	620	13984	53107
1992	6849	6391	5755	5171	4750	12067	360	336	303	351	398	13005	55737
1993	8933	8475	5857	5345	4917	15798	365	341	308	281	335	12105	59061
1994	6970	8512	5873	5360	5002	19018	367	343	309	282	263	10937	61236
1995	7055	6596	5975	5461	5102	22490	371	347	314	287	269	9841	63910

Table 13-25
Modest Increase Estimates: Total Number of Living Kidney Transplant
Recipients by Immunosuppressive Protocol by Year, 1983-1995

Year	Cyclosporine Therapy							Conventional Therapy							Grand Total
	1st	2nd	3rd	4th	5th	6th	Sub-	1st	2nd	3rd	4th	5th	6th	Sub-	
	Year	Year	Year	Year	Year	Year	Total	Year	Year	Year	Year	Year	Year	Total	
1983	675	0	0	0	0	0	675	3588	3388	2786	2424	2008	8888	23080	23755
1984	2794	661	0	0	0	0	3455	2390	3503	3375	2777	2454	10364	24883	28318
1985	4201	2641	629	0	0	0	7470	1756	2285	3334	3197	2699	11854	24905	32375
1986	5601	3854	2416	579	0	0	12451	1343	1839	2089	3078	3019	12628	23797	36248
1987	8128	5121	3489	2197	542	0	17476	813	1252	1504	1924	2889	13729	22109	39585
<hr/>															
1988	7180	5694	4681	3214	2076	510	23354	561	788	1153	1394	1819	14522	20214	43568
1989	8047	6598	5151	4263	3004	2400	29464	517	524	700	1070	1315	14173	18299	47763
1990	9037	7495	6044	4753	4032	5076	36478	476	485	483	650	1013	14195	17302	53740
1991	10146	8512	6873	5598	4514	8578	44221	534	448	446	451	620	14190	16690	60911
1992	11308	9464	7696	6268	5228	12067	52031	595	498	405	409	424	13005	15337	67368
1993	12741	10642	8668	7133	5957	16249	61389	671	580	456	375	390	12130	14582	75971
1994	14240	11870	9630	7907	6667	20396	70711	749	625	507	416	351	11011	13659	84370
1995	16096	13397	10881	8926	7518	25356	82173	847	705	573	470	396	9724	12715	94888

Table 13-26

13-57

population that is most likely to benefit from the Medicare Part C program. Rather than separate these patients according to the source of donor, we have combined both cadaveric and living-related donor recipients into a single set of tables. Tables 13-27, 13-28, and 13-29 present these data for the period 1979-1995, although each of the tables is identical for the period 1979-1987. Interestingly, Eggers (1988:223) estimates that in 1985 there were 19,610 kidney transplant recipients with a functioning graft. Our analyses reveals that there were 23,600 such patients in 1985, and 20,521 in 1984. These results are remarkably similar, even though the methods by which these numbers were determined were very different, and Eggers' estimates are biased down due to the underreporting of transplant forms in the years prior to 1983.

Number of Medicare-Eligible Living Kidney Transplant Recipients by Immunosuppressive Protocol

For costing purposes, it is critical that we separate the Medicare-eligible transplant recipients according to primary immunosuppressive protocol. As noted above, two categories of protocols are defined--cyclosporine therapy and conventional therapy. The costs associated with each of these protocols are very different.

Tables 13-30, 13-31 and 13-32 have been prepared to convey the results of our research. Once again, these tables reveal the gradual phasing out of conventional therapy in favor of cyclosporine therapy. The data for the period 1988 through 1995 are projected. All things considered, these tables are perhaps the most directly relevant to estimating the economic impact of Medicare Part C coverage.

Table 13-27

Medicare-Covered Base Case Estimates: Total Number of
Living Kidney Transplant Recipients
by Year, 1979-1995

<u>Year</u>	<u>First Year</u>	<u>Second Year</u>	<u>Third Year</u>	<u>Fourth Year</u>	<u>Fifth Year</u>	<u>Sixth Year +</u>	<u>Total</u>
1979	2474	2140	1992	779	759	2045	10189
1980	3171	2468	2105	1001	825	3091	12661
1981	3397	2834	2277	982	959	3368	13816
1982	3714	3001	2565	1067	934	3984	15264
1983	4261	3388	2786	1212	1004	4444	17096
1984	5184	4164	3375	1388	1227	5182	20521
1985	5957	4906	3963	1599	1349	5827	23600
1986	6944	5493	4505	1829	1510	6314	26595
1987	6941	6372	4992	2060	1715	6864	28945
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1988	7028	6460	5834	2304	1947	7516	31089
1989	7046	6478	5851	2667	2159	8286	32487
1990	7082	6583	5937	2701	2522	9612	34438
1991	7171	6690	6043	2754	2567	11281	36505
1992	7209	6728	6058	2761	2574	12536	37866
1993	7298	6816	6165	2813	2626	13952	39670
1994	7337	6854	6182	2821	2633	14977	40805
1995	7426	6943	6289	2874	2686	16066	42284

Assumes that 50% of patients continue to qualify for Medicare coverage after the third year with a successful graft (per Paul Eggers, 1988:223).

Table 13-28

Medicare-Covered Modest Case Estimates: Total Number of
Living Kidney Transplant Recipients
by Year, 1979-1995

<u>Year</u>	<u>First Year</u>	<u>Second Year</u>	<u>Third Year</u>	<u>Fourth Year</u>	<u>Fifth Year</u>	<u>Sixth Year +</u>	<u>Total</u>
1979	2474	2140	1992	779	759	2045	10189
1980	3171	2468	2105	1001	825	3091	12661
1981	3397	2834	2277	982	959	3368	13816
1982	3714	3001	2565	1067	934	3984	15264
1983	4261	3388	2786	1212	1004	4444	17096
1984	5184	4164	3375	1388	1227	5182	20521
1985	5957	4906	3963	1599	1349	5827	23600
1986	6944	5493	4505	1829	1510	6314	26595
1987	6941	6372	4992	2060	1715	6864	28945
<hr/>							
1988	7741	6460	5834	2304	1947	7516	31801
1989	8564	7123	5851	2667	2159	8286	34650
1990	9513	7981	6527	2701	2522	9636	38880
1991	10680	8960	7319	3025	2567	11384	43935
1992	11903	9962	8101	3339	2826	12536	48667
1993	13412	11203	9122	3754	3173	14190	54854
1994	14990	12495	10137	4162	3509	15703	60995
1995	16943	14102	11453	4698	3957	17540	68693

Assumes that 50% of patients continue to qualify for Medicare coverage after the third year with a successful graft (per Paul Eggers, 1988:223).

Table 13-29

Medicare-Covered Substantial Case Estimates: Total Number of
Living Kidney Transplant Recipients
by Year, 1979-1995

<u>Year</u>	<u>First Year</u>	<u>Second Year</u>	<u>Third Year</u>	<u>Fourth Year</u>	<u>Fifth Year</u>	<u>Sixth Year</u>	<u>Total</u>
1979	2474	2140	1992	779	759	2045	10189
1980	3171	2468	2105	1001	825	3091	12661
1981	3397	2834	2277	982	959	3368	13816
1982	3714	3001	2565	1067	934	3984	15264
1983	4261	3388	2786	1212	1004	4444	17096
1984	5184	4164	3375	1388	1227	5182	20521
1985	5957	4906	3963	1599	1349	5827	23600
1986	6944	5493	4505	1829	1510	6314	26595
1987	6941	6372	4992	2060	1715	6864	28945
<hr/>							
1988	8122	6460	5834	2304	1947	7516	32182
1989	10094	7470	5851	2667	2159	8286	36527
1990	12238	9392	6843	2701	2522	9612	43309
1991	15053	11507	8608	3171	2567	11066	51973
1992	18408	13998	10396	3923	2962	12220	61906
1993	22832	17287	12813	4812	3727	13891	75361
75361	28102	21193	15624	5836	4494	16144	91393
1995	35068	26372	19418	7229	5545	19123	112756

Assumes that 50% of patients continue to qualify for Medicare coverage after the third year with a successful graft (per Paul Eggers, 1988:223).

Table 13-30

13-62

Table 13-31

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Table 13-32
Medicare-Covered Substantial Increase Estimates: Total Number of Living
Kidney Transplant Recipients by Year, 1983-1995

Year	Cyclosporine Therapy							Conventional Therapy							
	1st	2nd	3rd	4th	5th	6th	Sub-	1st	2nd	3rd	4th	5th	6th	Sub-	Grand
	Year	Year	Year	Year	Year	Year	Total	Year	Year	Year	Year	Year	Year	Total	Total
1983	675	0	0	0	0	0	675	3588	3388	2788	1212	1004	4444	16420	17095
1984	2794	661	0	0	0	0	3455	2390	3503	3375	1388	1227	5182	17065	20520
1985	4201	2641	629	0	0	0	7471	1758	2265	3334	1599	1349	5827	16130	23601
1986	5601	3854	2418	290	0	0	12161	1343	1639	2089	1539	1510	6314	14434	26595
1987	6128	5121	3489	1098	271	0	10107	813	1252	1504	962	1445	6884	12840	28947
1988	7539	5694	4681	1607	1038	255	20814	583	766	1153	897	909	7261	11369	32183
1989	9498	6925	5151	2131	1502	1200	26407	596	544	700	535	657	7088	10118	36525
1990	11626	8833	6342	2377	2018	2538	33732	612	559	501	325	508	7074	9577	43309
1991	14300	10932	8095	2937	2257	4289	42810	753	575	513	234	310	6777	9162	51972
1992	17488	13298	9878	3688	2742	6034	53126	920	700	520	235	220	6186	8781	61907
1993	21690	16423	12172	4571	3503	8159	66518	1142	864	841	241	224	5731	8843	75361
1994	26697	20133	14843	5544	4269	10798	82282	1405	1060	781	292	225	5348	9111	91393
1995	33315	25053	18447	6868	5268	14124	103075	1753	1319	971	361	277	4975	9656	112731

Immunosuppressive Drug Costs

Obtaining information on the costs of immunosuppressive drugs is not as straightforward as it may first appear. Upon contacting the Pharmaceutical Manufacturer's Association (PMA), and other industry representatives, it became clear that pricing information fell into several categories. These included the following: (1) wholesale prices (2) direct pricing and (3) retail prices. We found it difficult to obtain information on each of these and, moreover, both wholesale and retail prices varied according to the manufacturer. This was particularly true in the case of generic products such as prednisone. Also, retail prices certainly vary according to region of the country.

Table 13-33 provides a listing of the primary immunosuppressive drugs used in transplantation, indicates their likely sources, whether a generic product is available, and the brand name of each product. As indicated, only prednisone and azathioprine are available from local retail pharmacies. With the exception of Minnesota antilymphocyte globulin (MALG), all other products are available at hospital pharmacies. Only prednisone has generic equivalents available. Specific pricing information on products made available to patients through hospital pharmacies is difficult to obtain and it is likely that prices vary depending upon the arrangements patients have made with hospital pharmacies. It is widely believed that many hospitals subsidize, to some extent, the costs associated with immunosuppressive drugs.

To standardize the pricing information for this report as much as possible, we chose to use the 1987 Redbook Drug Topics, Annual Pharmacist's Reference (1987) published by Medical Economics Company. This is the latest issue available. The 1988 edition will be published in April, 1989.

Table 13-33
Primary Immunosuppressive Drug Information

<u>Drug</u>	<u>Likely Source</u>	<u>Generic Brand Available?</u>	<u>Name</u>
Cyclosporine	Hospital Pharmacy	No	SANDIMMUNE
Prednisone	Local Retail Pharmacy	Yes	--
Azathioprine	Local Retail Pharmacy	No	IMURAN
Antithymocyte Globulin	Hospital Pharmacy	No	ATGAM
Antilymphocyte Globulin	University of Minnesota	No	MALG
OKT-3	Hospital Pharmacy	No	ORTHOCLONE

While the Redbook contains some information on direct prices or suggested retail prices, these are not available for all products. Therefore, we have chosen to use the average wholesale price (AWP) in calculating the costs associated with various immunosuppressive protocols. Even this exercise becomes somewhat confusing when it is realized that OKT-3 (ORTHOCLONE) does not appear in the Redbook. In discussing this matter with representatives of Ortho Pharmaceuticals, Raritan, New Jersey (Ms. Carolyn Pratt), we learned that OKT-3 is available at hospital pharmacies at a cost of \$350.00 per five mg units. Unfortunately, it is unclear whether this price is the actual charge to the patient, or whether the price varies from hospital to hospital. In the absence of this information, we assumed the price represented the AWP and that it did not vary from hospital to hospital. Also, it should be noted that OKT-3 is administered during an inpatient hospital stay and, therefore, the cost associated with the drug is not particularly crucial when estimating the costs associated with outpatient immunosuppressive drugs.

General Pricing Information--

Table 13-34 provides complete drug pricing information for all the primary immunosuppressive drugs used in kidney transplantation. All the products are identified and information appropriate to each has been incorporated into the table. Since Minnesota ALG is not an FDA-approved product, we have not included pricing information. Transplant centers using MALG have made special arrangements with the University of Minnesota to obtain the product. It is also noteworthy that for immunosuppressive protocols that incorporate a polyclonal antibody (MALG or ATGAM), we have

Table 13-34

Drug Pricing Information

<u>Product</u>	<u>Brand</u>	<u>Manufacturer</u>	<u>Quantity</u>	<u>NDC/Prod.No.</u>	<u>Average Wholesale Price (AWP)</u>	<u>AWP Per Milligram</u>
Cyclosporine	Sandimmune	Sandoz	Sol., ORAL, 100mg/ml, 50 ml ea.	0078-0110-22	\$161.70	\$ 0.0320*
Prednisone	---	Lederle	Tab, 5mg., 1000's ea.	0005-3458-34	\$ 21.10	\$ 0.0042*
Azathioprine	Imuran	Burroughs/ Wellcome	Tab, 50mg., 100's ea.	0081-0597-55	\$ 59.16	\$ 0.0118*
Antithymocyte Globulin	Atgam	Upjohn	Amp, 50mg./ml., 5ml ea.	0009-0926-01	\$ 87.50	\$ 0.3500*
OKT-3	Orthoclone	ORTHO	Amp, 5 mg./5 ml., 5 ml ea.		\$350.00	\$70.00**

SOURCE: *1987 Redbook: Drug Topics, Annual Pharmacist's Reference. Oradell, N.J., Medical Economics Co., Inc., 1987: pages 143, 339, 484 and 524.

**Ms. Carolyn Pratt, Ortho Pharmaceuticals, Raritan, N.J. Ph. (201) 788-5264.

used the pricing information for ATGAM. Also, it should be noted that prednisone is available at both greater and lesser expense than shown in the table. We chose Lederle as the product manufacturer because Lederle also has plans to produce cyclosporine once the patent has expired (1992).

In reviewing Table 13-34, it is apparent that we have reported drug pricing according to the cost per milligram. This was necessary to allow us to compute the average daily cost of immunosuppressive drugs by various protocols, as will be described below. As noted above, average wholesale prices are indicated based on the Redbook with the exception of ORTHOCLONE, the cost of which was provided by Ms. Carolyn Pratt (telephone 201-788-5265).

HCFA actuaries will have to decide how to transform the information into a form that will meet their needs. Obviously, one could obtain pricing information from hospitals throughout the country in an effort to compute an average retail price. For example, calling the ten largest transplant center hospital pharmacies would produce the required information. An average of these prices could be calculated and these could then be incorporated into the estimation procedures. It is unclear, however, exactly how much fine tuning the HCFA actuaries require.

Daily Per Patient Costs by Immunosuppressive Protocol--

A thorough review of the literature permits us to construct the immunosuppressive protocols in use today and to calculate both the daily and annual costs associated with each. The major protocols in use today have been identified above. These are as follows:

- Conventional immunosuppressive therapy (pre-1984).
- Double-drug cyclosporine immunosuppressive therapy.
- Triple-drug cyclosporine immunosuppressive therapy,
- Quadruple-drug cyclosporine immunosuppressive therapy.

We have also described two additional protocols--a European variation of triple-drug cyclosporine immunosuppressive therapy and a prophylactic OKT-3 triple drug cyclosporine immunosuppressive therapy. The combination of drugs used in these various protocols has been listed in Table 13-1.

We have prepared several tables that identify the various drugs used in the protocols, the dosages required both initially and for maintenance therapy, the per unit drug cost, and the daily cost for both initial and maintenance therapy. Tables 13-35 through 13-40 contain this information, and are based on a 70 kilogram person (154.32 lbs). The sources for the dosages of drugs are indicated on each table. Dosages are indicated as milligram per day as well as milligram per kilogram per day. With respect to the time periods during which the various protocols are followed, we have distinguished between the initial and the maintenance periods. The initial period consists of the first 60 days posttransplant. The maintenance period is that period commencing on day 61 posttransplant.

Tables 13-41 through 13-46 have been prepared as an indication of the daily drug quantities and costs according to patient status (inpatient or outpatient). Unless otherwise indicated, the average length of the patient's initial hospital stay is assumed to be 20 days, the national average in 1985.

At the bottom of each table we have summarized total immunosuppressive drug costs according to inpatient stay and outpatient status during Year One. Also, we have estimated the costs associated with each protocol after Year One for all subsequent posttransplant years.

Table 13-35

Conventional Immunosuppressive Therapy (Azathioprine and Prednisone): Agents, Dosages, and Costs¹

Immunosuppressive Drug	Drug Protocol ²		Per Unit Drug Cost	Daily Cost	
	<u>Initial</u>	<u>Maintenance</u>		<u>Initial</u>	<u>Maintenance</u>
Prednisone	140 mg/d 2.0 mg/kg/d	17.5 mg/d .25 mg/kg/d	\$0.004/mg	\$0.56	\$0.07
Azathioprine	350 mg/d 5 mg/kg/d	175 mg/d 2.5 mg/kg/d	\$0.012/mg	\$4.20	\$2.10
Antilymphocyte ³ Globulin	2100 mg/d 30 mg/kg/d	-0- -0-	\$0.350/mg	\$735.00	-0-

¹Based on protocols in use at University of Minnesota and the University of Pittsburgh (see references 70 and 71).

²Based on 70 kg person (= 154.32 lbs.).

³Used for 14 days at University of Minnesota during inpatient stay.

Table 13-36

Double-Drug Cyclosporine Immunosuppressive Therapy: Agents, Dosages, and Costs¹

Immunosuppressive Drug	Drug Protocol ²		Per Unit Drug Cost	Daily Cost	
	Initial	Maintenance		Initial	Maintenance
Prednisone	140 mg/d	10-15 mg/d*	\$0.004/mg	\$0.56	\$0.04 to \$0.06
	2.0 mg/kg/d*	.15-.22 mg/kg/d			
Cyclosporine	700-980 mg/d	700 mg/d	\$0.032/mg	\$22.40 to \$31.36	\$22.40
	12-14 mg/kg/d*	10 mg/kg/d*			

¹Based on protocols in use at the University of Texas--Houston and the University of Pittsburgh (see Lorber *et al.*, 1987:35; Gordon *et al.*, 1987:44).

²Based on 70 kg person (= 154.32 lbs.).

*As specified in published reports.

Table 13-37

United States' Variation of Triple-Drug Cyclosporine Immunosuppressive Therapy:
Agents, Dosages and Costs¹

Immunosuppressive Drug	Drug Protocol ²		Per Unit Drug Cost	Daily Cost	
	<u>Initial</u>	<u>Maintenance</u>		<u>Initial</u>	<u>Maintenance</u>
Prednisone	2 mg/kg/d* 140 mg/d	.5 mg/kg/d* 35 mg/d	\$0.004/mg	\$0.56	\$0.14
Antilymphocyte ³ Globulin	15 mg/kg/d* 1050 mg/d	- 0 - - 0 -	\$0.350/mg	\$367.50	---
Cyclosporine ⁴	10 mg/kg/d 700 mg	10 mg/kg/d* 700 mg/d	\$0.032/mg	\$ 22.40	\$22.40
Azathioprine	2 mg/kg/d* 140 mg/d	- 0 -	\$0.012/mg	\$1.68	---

¹ Based on protocols in use at the Ohio State University (see Sommer et al., 1986:69; Ferguson et al., 1987:195; Ferguson, 1988:285).

² Based on 70 kg person (= 154.32 lbs)

³ Used for 5 to 10 days on inpatient basis only

⁴ Starting on day 7 of initial hospital stay

* As specified in published reports

Table 13-38

European Variation of Triple-Drug Cyclosporine Immunosuppressive Therapy:
Agents, Dosages, and Costs¹

Immunosuppressive Drug	Drug Protocol ²		Per Unit Drug Cost	Daily Cost	
	Initial	Maintenance		Initial	Maintenance
Prednisone	30 mg/d* .43 mg/kg/d	35 mg/d* .5 mg/kg/d	\$0.004/mg	\$0.12	\$0.14
Cyclosporine	280-500 mg/d 4.0-8.0 mg/kg/d*	140-430 mg/d 2.0-6.0 mg/kg/d*	\$0.032/mg	\$8.96 to \$16.00	\$4.48 to \$13.76
Azathioprine	70 mg/d 1.0 mg/kg/d*	70 mg/d 1.0 mg/kg/d*	\$0.012/mg	\$0.84	\$0.84

¹Based on protocols reviewed by Land (see reference 76).

²Based on 70 kg person (= 154.32 lbs.).

*As specified in published reports.

Table 13-39

Prophylactic OKT-3 Triple Drug Cyclosporine Therapy: Agents, Dosages, and Costs¹

Immunosuppressive Drug	Drug Protocol ²		Per Unit Drug Cost	Daily Cost	
	Initial	Maintenance		Initial	Maintenance
Prednisone	.5 mg/kg/d* 35 mg/d	.5 mg/kg/d* 35 mg/d	\$0.004/mg	\$0.14	\$0.14
Azathioprine	1-2 mg/kg/d* 70-140 kg/d	1-2 mg/kg/d* 70-140 kg/d	\$0.012/mg	\$1.47 to 1.68	\$1.47 to 1.68
Cyclosporine	12 mg/kg/d* ³ 840 mg/d	6 mg/kg/d	\$0.032/mg	\$26.88	\$13.44
OKT-3	5 mg/d* ⁴	-0-	\$70.00/mg	\$350.00	---

¹ Based on Shield et al. (see Shield et al., 1988:190).² Based on 70 kg person (= 154.32 lbs.).³ Started on day 11 of treatment.⁴ 14 Consecutive days on inpatient basis.

* As specified in published report.

Table 13-40
Quadruple-Drug Cyclosporine Immunosuppressive Therapy: Agents, Dosages, and Costs¹

Immunosuppressive Drug	Drug Protocol ²		Per Unit Drug Cost	Daily Cost	
	Initial	Maintenance		Initial	Maintenance
Prednisone	30 mg/d* .43 mg/kg/d	10-15 mg/d* .15-.22 mg/kg/d	\$0.004/mg	\$0.12	\$0.04 to \$0.06
Antilymphocyte ³ Globulin	1400 mg/d 20 mg/kg/d*	-0- -0-	\$0.350/mg	\$490.00	--
Cyclosporine	550-1120 mg/d 8-16 mg/kg/d*	280-560 mg/d 4-8 mg/kg/d*	\$0.032/mg	\$17.60 to \$35.84	\$8.96 to \$17.92
Azathioprine	25-30 mg/d* .36-.43 mg/kg/d	70 mg/d 1.0 mg/kg/d*	\$0.012/mg	\$0.30 to \$0.36	\$0.84

¹Based on protocols in use at the University of Wisconsin (Stratta *et al.*, 1987:183; 1988:40; Sollinger *et al.*, 1986:16).

²Based on 70 kg person (= 154.32 lbs.).

³Used for 5 to 10 days on inpatient basis only.

*As specified in published reports.

Table 13-41

Conventional Immunosuppression (Azathioprine and Prednisone):
Drug Quantities and Costs According to Patient Status

Protocol	Drug Quantities and Costs According to Patient Status					
	Inpatient			Outpatient		
Conventional Immunosuppression	PRED	AZA	ALG	PRED	AZA	
(1) Drug Quantities (mg/d)						
0-20 days Post Tx	140	350	2,100	-	-	-
21-60 days Post Tx	-	-	-	140	350	350
61-365 days Post Tx	-	-	-	18	175	175
366-730 days Post Tx	-	-	-	18	175	175
(2) Drug Costs (\$)						
0-20 days Post Tx	11	84	10,290	-	-	-
21-60 days Post Tx	-	-	-	22	168	168
61-365 days Post Tx	-	-	-	21	641	641
366-730 days Post Tx	-	-	-	26	767	767
<hr/>						
<hr/>						
Total Inpatient Costs Year 1 (w/o ALG)						\$ 95
Total Inpatient Costs Year 1 (w/ALG)						10,385
Total Outpatient Costs Year 1						852
Grand Total Year 1 (w/o ALG)						947
Grand Total Year 1 (w/ALG)						11,237
Total Annual Costs After Year 1						793

Table 13-42

Double Drug Cyclosporine Therapy: Drug Quantities and Costs
According to Patient Status

Protocol		Drug Quantities and Costs According to Patient Status			
		Inpatient		Outpatient	
Double-Drug Cyclosporine Therapy		CSA	PRED	CSA	PRED
(1) Drug Quantities (mg/d)					
0-20 days Post Tx		980	140	-	-
21-60 days Post Tx		-	-	980	140
61-365 days Post Tx		-	-	700	15
366-730 days Post Tx		-	-	700	15
(2) Drug Costs (\$)					
0-20 days Post Tx		627	11	-	-
21-60 days Post Tx		-	-	1254	22
61-365 days Post Tx		-	-	6832	18
366-730 days Post Tx		-	-	8176	22
Total Inpatient Costs Year 1		\$ 638		\$ 459	
Total Outpatient Costs Year 1		8,126		7,742	
Grand Total Year 1		8,764		8,201	
Total Annual Costs After Year 1		8,198		8,191	

Table 13-43

United States' Variation of Triple Drug Cyclosporine Therapy: Drug Quantities and Costs
According to Patient Status

Drug Quantities and Costs According to Patient Status

Protocol	Inpatient						Outpatient		
	CSA	PRED	AZA	ALG	CSA	PRED	CSA	PRED	
<u>United States Variation of Triple Drug Cyclosporine Therapy</u>									
(1) Drug Quantities (mg/d)									
0-20 days Post Tx	700	140	140	1050	-	-	-	-	-
21-60 days Post Tx	-	-	-	-	700	140	700	140	
61-365 days Post Tx	-	-	-	-	700	35	700	35	
366-730 days Post Tx	-	-	-	-	700	35	700	35	
(2) Drug Costs (\$)									
0-20 days Post Tx	314	11	34	3675	-	-	-	-	-
21-60 days Post Tx	-	-	-	-	896	22	896	22	
61-365 days Post Tx	-	-	-	-	6832	6	6832	6	
366-730 days Post Tx	-	-	-	-	8176	51	8176	51	

	High	Low
Total Inpatient Costs Year 1	\$4,034	\$2,197
Total Outpatient Costs Year 1	7,756	7,756
Grand Total Year 1	11,790	9,953
Total Annual Costs After Year 1	8,227	8,227

Table 13-44

European Variation of Triple Drug Cyclosporine Therapy:
Drug Quantities and Costs According to Patient Status

Protocol	Drug Quantities and Costs According to Patient Status					
	Inpatient			Outpatient		
	<u>CSA</u>	<u>PRED</u>	<u>AZA</u>	<u>CSA</u>	<u>PRED</u>	<u>AZA</u>
<u>European Variation of Triple-Drug Cyclosporine Therapy</u>						
(1) Drug Quantities (mg/d)						
0-20 days Post Tx	500	30	70	-	-	-
21-60 days Post Tx	-	-	-	500	30	70
61-365 days Post Tx	-	-	-	430	35	70
366-730 days Post Tx	-	-	-	430	35	70
(2) Drug Costs (\$)						
0-20 days Post Tx	320	2	17	-	-	-
21-60 days Post Tx	-	-	-	640	5	34
61-365 days Post Tx	-	-	-	4,197	43	256
366-730 days Post Tx	-	-	-	5,840	51	307
<hr/>						
<hr/>						
	<u>High</u>			<u>Low</u>		
Total Inpatient Costs Year 1	\$ 339			\$ 198		
Total Outpatient Costs Year 1	5,175			2,062		
Grand Total Year 1	5,514			2,260		
Total Annual Costs After Year 1	6,198			1,993		

Table 13-45

Prophylactic OKT-3 Triple Drug Cyclosporine Therapy: Agents, Dosages, and Costs

Drug Quantities and Costs According to Patient Status									
Protocol	Inpatient				Outpatient				
	CSA	PRED	AZA	OKT-3	CSA	PRED	AZA		
Prophylactic OKT-3 Therapy									
(1) Drug Quantities (mg/d)									
0-20 days Post Tx	840	35	140	5	-	-	-		
21-60 days Past Tx	-	35	140	5	840	35	140		
61-365 days Past Tx	-	-	-	-	420	35	70		
366-730 days Past Tx	-	-	-	-	420	35	70		
(2) Drug Costs (\$)									
0-20 days Post Tx	269	3	34	4900	-	-	-		
21-60 days Past Tx	-	-	-	-	1,075	6	67		
61-365 days Past Tx	-	-	-	-	4,099	43	512		
366-730 days Past Tx	-	-	-	-	4,906	51	613		
Total Inpatient Costs Year 1									
Total Outpatient Costs Year 1									
Grand Total Year 1									
Total Annual Costs After Year 1									
			HIGH				LOW		
Total Inpatient Costs Year 1	\$ 5,206				\$ 5,201				
Total Outpatient Costs Year 1	\$ 5,802				\$ 5,730				
Grand Total Year 1	\$11,008				\$10,931				
Total Annual Costs After Year 1	\$ 5,570				\$ 5,494				

Table 13-46

Quadruple Drug Cyclosporine Therapy: Drug Quantities and Costs
According to Patient Status

Drug Quantities and Costs According to Patient Status									
Protocol	Quadruple-Drug Cyclosporine Therapy	Inpatient				Outpatient			
		CSA	PRED	AZA	ALG	CSA	PRED	AZA	
(1) Drug Quantities (mg/d)									
	0-20 days Post Tx	1120	30	30	1400	-	-	-	
	21-60 days Past Tx	-	-	-	-	1120	30	30	
	61-365 days Past Tx	-	-	-	-	560	15	70	
	366-730 days Past Tx	-	-	-	-	560	15	70	
(2) Drug Costs (\$)									
	0-20 days Post Tx	717	2	7	4900	-	-	-	
	21-60 days Past Tx	-	-	-	-	1,434	5	14	
	61-365 days Past Tx	-	-	-	-	5,466	18	256	
	366-730 days Past Tx	-	-	-	-	6,541	22	307	

	HIGH	LOW
Total Inpatient Costs Year 1	\$ 5,626	\$ 2,810
Total Outpatient Costs Year 1	\$ 7,193	\$ 3,722
Grand Total Year 1	\$12,819	\$ 6,532
Total Annual Costs After Year 1	\$ 6,870	\$ 3,592

Summary of Total Annual Per Patient Immunosuppressive Drug Costs--

All of the foregoing information on immunosuppressive drug costs can be distilled readily in a manner that is quite straightforward. In Table 13-47 we have summarized total annual costs by protocol for Year One (inpatient and outpatient), as well as all subsequent years. However, of the several protocols listed in Table 13-47, only six of them would be considered as major protocols in use in the United States today. These protocols, and the costs associated with their use are listed in Table 13-48. Since very few patients today receive conventional therapy, we suggest that only the subsequent year annual costs be factored into the Medicare Part C calculations. Double-drug and triple-drug cyclosporine therapy are the two most widely used protocols in the United States, with quadruple-drug cyclosporine therapy attracting a modest degree of attention. As shown, there is very little difference between the subsequent year annual costs for double-drug and triple-drug cyclosporine therapy. Quadruple-drug cyclosporine therapy has subsequent year annual costs of \$6,870. Clearly, the least expensive protocol of all is conventional immunosuppressive therapy at \$793. In itself, this figure is misleading since the cost-effectiveness of cyclosporine therapy is believed to exceed that associated with conventional therapy, as reported by the National Task Force on Organ Transplantation (1985). (It is noteworthy, however, that the Task Force assumed that all patients on cyclosporine therapy would be converted to conventional therapy within one year posttransplant. Eggers has recently argued that the cost-effectiveness of cyclosporine in the out years is very much in doubt. He feels that cyclosporine is basically an added cost with no observable increase in survival.) In short, the protocols included in Table 13-48 are not equally effective, and should not be construed as such. Based on

Table 13-47

Summary of Drug Costs According to Immunosuppressive Protocol

Immunosuppressive Protocol	Costs by Patient Status			Total Year 1 Costs	Subsequent Year Annual Costs
	Inpatient Year 1	Outpatient Year 1			
Conventional Immunosuppression					
Without Antithymocyte Globulin	\$ 95	\$ 852	\$ 947	\$ 793	
With Antithymocyte Globulin	\$10,385	\$ 852	\$11,237	\$ 793	
Double-Drug Cyclosporine Therapy*	\$ 638	\$ 8,126	\$ 8,764	\$ 8,198	
Triple-Drug Cyclosporine Therapy					
U.S. Variation*	\$ 4,034	\$ 7,756	\$11,790	\$ 8,227	
European Variation*	\$ 339	\$ 5,175	\$ 5,514	\$ 6,198	
Prophylactic OKT-3 Variation*	\$ 5,206	\$ 5,802	\$11,008	\$ 5,570	
Quadruple-Drug Cyclosporine Therapy*	\$ 5,626	\$ 7,193	\$12,819	\$ 6,870	

* High cost estimates only, see Tables 13-42 through 13-46 for low cost estimates.

Table 13-48

Costs Associated with Major Immunosuppressive Protocols in Use in the United States*

<u>Immunosuppressive Protocol</u>	<u>First Year Costs</u>		<u>Subsequent Year Annual Costs</u>
	<u>Inpatient</u>	<u>Outpatient</u>	
Conventional Immunosuppression			
Without Antithymocyte Globulin	\$ 95	\$ 852	\$ 793
With Antithymocyte Globulin	\$10,385	\$ 852	\$ 793
Double-Drug Cyclosporine Therapy	\$ 638	\$ 8,126	\$ 8,198
Triple-Drug Cyclosporine Therapy			
U.S. Variation,	\$ 4,034	\$ 7,756	\$ 8,227
Quadruple-Drug Cyclosporine Therapy	\$ 5,626	\$ 7,193	\$ 6,870

* High cost estimates only, see Tables 13-42 through 13-46 for low cost estimates.

our current research, it appears that triple-drug and quadruple-drug cyclosporine therapy are equally cost-effective, both being more effective than double-drug cyclosporine therapy. Conventional therapy is the least effective of all protocols. Interestingly, if one considers the uninflated costs associated with double-drug, triple-drug and quadruple-drug cyclosporine therapy, both including and excluding inpatient drug costs, over a five year time frame the costs are quite similar, as shown in Table 13-49.

Drug Costs Based on This Study

In this study we very systematically collected data on immunosuppressive drug protocols and the quantities of drugs used by each of the participating transplant teams. Moreover, these data were obtained at the individual patient level at three-month intervals beginning with the period of the transplant (hereafter referred to as the "initial" period). In doing this, we found there was considerable variability in the quantities of drugs used and these quantities were often inconsistent with published data on transplant immunosuppressive protocols.

In this section of the chapter we will briefly highlight our major findings. In addition, we will recalculate the annual per patient immunosuppressive drug costs, assuming these protocols and the quantities of drugs administered are similar to those actually in use today. It will readily become evident how markedly total drug costs vary depending upon the quantities of drugs required.

The major drug protocols followed in the current study are as follows:

INITIAL

CSA + PRED

AZA + PRED + ALG

MAINTENANCE

CSA + PRED

CSA + PRED + AZA

Table 13-49

Immunosuppressive Drug Costs Over a Five-Year Time Frame

<u>Immunosuppressive Protocol</u>	<u>Inpatient and Outpatient</u>	<u>Outpatient Only</u>
Double-Drug Cyclosporine	\$ 41,556	\$ 40,918
Triple-Drug Cyclosporine	44,702	40,668
Quadruple-Drug Cyclosporine	40,299	34,673

As indicated, those centers which begin with CSA + PRED during the initial period continue to use CSA + PRED during the maintenance period. Those centers which begin with a protocol consisting of AZA + PRED + ALG drop the ALG and add CSA. Some teams have dropped the ALG and AZA and use CSA and PRED as their maintenance protocol. The majority of patients in the present study, however, continue during the maintenance period with CSA + PRED + AZA.

Table 13-50 summarizes the average quantities of drugs (mg/kg/d) under each of the two initial immunosuppressive protocols studied according to several time periods. As shown, with the exception of dropping ALG and the continuation of AZA at 0.9 to 1.0 mg/kg/d under the AZA + PRED + ALG protocol, all other drugs under each of the two initial protocols are tapered. The extent to which these drugs are tapered is remarkable, given published reports.

In Table 13-51 we have estimated the total milligrams of drug required per day for a 70 kilogram patient according to various time periods. We have assumed that ALG will be discontinued within 14 days (range=8 to 17 days), the average length of stay for a renal transplant recipient. This table, of course, also reveals the considerable tapering of drug dosages.

In order to calculate total drug costs by time periods, we must define each time period of interest. These are as follows: (1) initial, (2) 3 months, (3) 6 months, (4) 9 months, and (5) 12 months. We, again, have assumed a twenty-day length of hospital stay for the initial period. Our estimates are summarized in Table 13-52.

To simplify the cost estimation process, we have prepared Table 13-53. This table shows the total milligrams of drug required by a 70 kilogram person for each of the time periods of interest. We have also included an estimate for a stable maintenance period. These estimates continue to reflect the relative

Table 13-50

Milligrams Per Kilogram Per Day of Drugs Required
According to Immunosuppressive Protocol and Time Period

<u>mg/kg/d of Immunosuppressive Drugs by Initial Protocol</u>						
<u>Time Period</u>	<u>AZA + PRED + ALG</u>				<u>CSA + PRED</u>	
	<u>CSA</u>	<u>PRED</u>	<u>AZA</u>	<u>ALG</u>	<u>CSA</u>	<u>PRED</u>
Initial (0-60 Days)						
0-20 Days	7.7	.51	1.0	11.7	12.2	.52
21-60 Days	7.7	.51	1.0	11.7	12.2	.52
3 Months						
61-90 Days	5.5	.31	0.9	0	8.1	.30
6 Months						
91-182 Days	4.6	.24	1.0	0	6.8	.24
9 Months						
183-275 Days	4.0	.20	0.9	0	6.2	.23
12 Months						
276-368 Days	3.5	.19	0.9	0	4.9	.22

Table 13-51

Milligrams of Drug Per Day Required by a 70 Kilogram Person According
to Immunosuppressive Protocol and Time Period

<u>mg/d of Immunosuppressive Drugs by Initial Protocol</u>						
<u>Time Period</u>	<u>AZA + PRED + ALG</u>				<u>CSA + PRED</u>	
	<u>CSA</u>	<u>PRED</u>	<u>AZA</u>	<u>ALG</u>	<u>CSA</u>	<u>PRED</u>
Initial						
0-20 Days	539	38	70	819	854	36
21-60 Days	539	38	70	0	854	36
3 Months	385	22	63	0	567	21
6 Months	322	17	70	0	476	17
9 Months	280	14	63	0	434	16
12 Months	245	13	63	0	343	15
Maintenance	245	13	63	0	343	15

¹ Based on 70 kg person (=154.32 lbs.)

Table 13-52
Definition of Time Periods

<u>Transplant Time Period</u>	<u>Range of Days</u>	<u>Number of Days in Range</u>
Initial		
0-20 Days	0-20	20
21-60 Days	21-60	40
3 Months	61-90	30
6 Months	91-182	91
9 Months	183-275	92
12 Months	276-368	92
		Total = 365

Table 13-53

Total Milligrams of Drug Required During the Entire Time Period
According to Initial Immunosuppressive Protocol

Time Period	Total Milligrams of Immunosuppressive Drugs by Period and Initial Protocol					
	AZA + PRED + ALG			CSA + PRED		
	CSA*	PRED	AZA	ALG	CSA	PRED
Initial (Days 0-60)						
0-20 Days (20 Days)	7,546	760	1,400	11,466	17,080	720
21-60 Days (40 Days)	21,560	1,520	2,800	0	34,160	1,440
3 Months (Days 61-90)						
61-90 Days (30 Days)	11,550	660	1,890	0	17,010	630
6 Months (Days 91-182)						
91-182 Days (91 Days)	29,302	1,547	6,370	0	43,316	1,547
9 Months (Days 183-275)						
183-275 Days (92 Days)	25,760	1,288	5,796	0	39,928	1,472
12 Months (Days 276-365)						
276-365 Days (92 Days)	22,540	1,196	5,796	0	31,556	1,380
Maintenance (365 Days)	89,425	4,745	22,995	0	125,195	5,475

* CSA initiated on seventh day posttransplant

tapering of the various immunosuppressive agents. ALG is removed from the triple drug therapy induction protocol, but may, again, be reintroduced to treat a rejection episode. The focus of this analysis, however, is not on treating rejection episodes.

In Table 13-54, we have provided costs of immunosuppressive drugs based on the 1987 Redbook, as summarized previously in Table 13-34.

Finally, in Table 13-55 we have summarized the cost data according to inpatient, outpatient, total first year, and subsequent year costs. As noted previously, inpatient costs are much higher for the AZA + PRED + ALG protocol compared with the CSA + PRED protocol (\$4,274 versus \$550). However, outpatient year costs are higher for the CSA + PRED protocol than for the AZA + PRED + ALG protocol (\$5,338 versus \$3,899). Ultimately, total first year costs favor CSA + PRED as opposed to AZA + PRED + ALG (\$5,888 versus \$8,173).

Although the AZA + PRED + ALG protocol is more costly during year one, it is less costly than the CSA + PRED protocol during subsequent years (\$3,157 versus \$4,028). This cost savings is largely a function of the reduced dosage of cyclosporine due to the use of multiple immunosuppressive agents. However, over a five-year period, there is relatively little difference between the cost of double- and triple-drug therapy. The five-year cost of double-drug therapy is \$22,000 and for triple-drug therapy \$20,801.

What is most striking about these cost figures is the significant decrease in the costs of immunosuppressive drugs based on the tapering of the dosages of cyclosporine. The published literature indicates that dosages are much higher than those in use today. Thus, costs are proportionately lower. Table 13-56 summarizes these data based on computations and estimates provided in

Table 13-54

Total Immunosuppressive Drug Costs by Time Period
According to Initial Immunosuppressive Protocol

Time Period	Total Costs of Immunosuppressive Drugs by Period and Initial Protocol					
	AZA + PRED + ALG			CSA + PRED		
	<u>CSA</u>	<u>PRED</u>	<u>AZA</u>	<u>ALG</u>	<u>TOTAL</u>	<u>TOTAL</u>
(Cost per milligram)	(\$.032)	(\$.004)	(\$.012)	(\$.350)	(--)	(\$.032) (\$.004) (--)
Initial (Days 0-60)						
0-20 Days (20 Days)	241	3	17	4,013	4,274	3 550
21-60 Days (40 Days)	690	6	34	0	730	6 1,099
3 Months (Days 61-90)						
61-90 Days (30 Days)	370	3	23	0	396	3 547
6 Months (Days 91-182)						
91-182 Days (91 Days)	938	6	134	0	1,078	6 1,392
9 Months (Days 183-275)						
183-275 Days (92 Days)	824	5	70	0	899	6 1,284
12 Months (Days 276-365)						
276-365 Days (92 Days)	721	5	70	0	796	6 1,016
Maintenance (365 Days)	2,862	19	276	0	3,157	22 4,028

Table 13-55

Summary of Drug Costs According to Immunosuppressive Protocol

Immunosuppressive Protocol Initial Maintenance	Year 1 Costs by Patient Status			Total Year 1 Costs	Subsequent Year Annual Costs
	Inpatient Year 1	Outpatient Year 1			
(1) CSA+PRED CSA+PRED	\$ 550	\$ 5,338		\$ 5,888	\$ 4,028
(2) AZA+PRED+ALG CSA+AZA+PRED	\$ 4,274	\$ 3,899		\$ 8,173	\$ 3,157

Table 13-56

Summary of Drug Costs According to Immunosuppressive Protocol:
Historical and Contemporary

Immunosuppressive Protocol Initial Maintenance	Year 1 Costs by Patient Status			Total Year 1 Costs	Subsequent Year Annual Costs
	Inpatient Year 1	Outpatient Year 1			
(1) CSA+PRED					
Historical ¹	\$ 638	\$ 8,126		\$ 8,764	\$ 8,198
Contemporary ²	\$ 550	\$ 5,338		\$ 5,888	\$ 4,028
Difference	- 88	- 2,788		- 2,876	- 4,170
(2) AZA+PRED+ALG CSA+AZA+PRED					
Historical ¹	\$ 4,034	\$ 7,756		\$11,790	\$ 8,227
Contemporary ²	\$ 4,274	\$ 3,899		\$ 8,173	\$ 3,157
Difference	+ 240	- 3,857		- 3,617	- 5,070

¹ Based on Table 13-48² Based on Table 13-55

this chapter and in Chapter 5. The costs based on published reports are referred to as "historical," and those based on this study as "contemporary." The row referred to as "difference" indicates the difference between the historical and the contemporary data.

As indicated in Table 13-56, total first year costs under the CSA + PRED protocol have been reduced by 33 percent and those under the AZA + PRED + ALG protocol by 31 percent. Subsequent year annual costs have been reduced even more markedly--by 51 percent under the CSA + PRED protocol and by 62 percent under the AZA + PRED + ALG protocol.

Clearly, based on this analysis, the costs associated with transplant immunosuppression have been reduced considerably, at least based on the experience of the five centers that participated in this study. These results must be interpreted with caution, however, as they are based on the average dosages of drugs administered. Some patients, of course, had higher dosages than others, and some had lower. Nonetheless, there has been a general trend in the direction of minimizing the quantity of immunosuppressive agents administered to transplant recipients due to the untoward consequences associated with overimmunosuppression.

Suggestions Regarding Immunosuppressive Drug Costs

A concerted attempt has been made here to provide reasonable estimates of the cost of immunosuppressive drugs according to protocols currently being used in the United States. In the application of these data, several cautions are in order. These are described below.

First, the costs of drugs associated with the treatment of rejection have not been factored into the total annual costs. Nearly 50 percent of all

kidney transplant recipients will have a rejection episode during the first year posttransplant, usually within the first three months. Such an episode is usually treated with: (1) pulse therapy consisting of administering higher doses of prednisone for a short period of time, usually on an outpatient basis, (2) OKT-3 therapy wherein a patient is admitted to the hospital and receives an intensive course of ORTHOCLONE OKT-3, and (3) antithymocyte or antilymphocyte globulin may also be administered, once again on an inpatient basis in most instances. Pulse therapy is relatively inexpensive, while ORTHOCLONE OKT-3, ALG, and ATG can be quite expensive. For example Monaco and co-workers report that the standard ORTHOCLONE OKT-3 treatment course for acute rejection is five mg/d of ORTHOCLONE OKT-3 by intravenous push for 10 to 14 days, with the dosages of other immunosuppressive drugs reduced during this period, with resumption to maintenance levels thereafter. Based on this protocol, the cost per patient for the treatment of rejection by ORTHOCLONE OKT-3 alone is between \$3,500 and \$4,900 (Monaco *et al.*, 1987:28). Clearly, the treatment of rejection can add considerably to the first year immunosuppressive drug costs of transplant recipients. These costs have not been factored into our estimates, largely because they are inpatient costs and would not be subject to Medicare Part C considerations.

A second area of concern in projecting costs relates to the eventual use of ORTHOCLONE OKT-3 prophylactically. At this time it is unclear whether OKT-3 will become a standard part of the immunosuppressive therapy for transplant recipients. Most frequently OKT-3 is used to treat rejection. We have, however, provided estimates of the costs associated with the prophylactic use of OKT-3.

A third problem area relates to the distribution of protocols within the patient population. We have no way of documenting how many patients are on double-, triple-, or quadruple-drug cyclosporine therapy. However, since there are rather modest cost differences in the protocols used posttransplant, this concern is likely to be of little consequence.

Finally, and perhaps most importantly, there has been much interest in what are generally referred to as conversion protocols (Task Force on Organ Transplantation, 1985). Under these protocols patients are eventually taken off cyclosporine, usually within three, six, nine or twelve months posttransplant (Hall *et al.*, 1988:1499; First *et al.*, 1986:132; Fries *et al.*, 1988:130; Deierhoi *et al.*, 1987:71; Broyer *et al.*, 1987:3582; Slapak, 1987:958; Lund *et al.*, 1983:2857; Lennard *et al.*, 1987:3594; Hoitma *et al.*, 1987:584; Keown, 1987:1; Henriksen, 1986:1002; Gonwa *et al.*, 1987:225; Flechner *et al.*, 1985:276; Shapira *et al.*, 1986:1261). While some reports indicate that conversion can be accomplished successfully, the results are often inconsistent (See Chapter 3). Several reports, for example, indicate that acute rejection following conversion is unavoidable. While there are many reasons to convert patients from cyclosporine, a major consideration is economic. The argument favoring cyclosporine conversion under these circumstances is simple. The primary benefits associated with cyclosporine during the early postoperative period are obtained, and later cost savings are realized.

While the National Task Force on Organ Transplantation (1985) assumed that conversion was likely to occur uniformly in the future, this assumption has proven incorrect. Very few kidney transplant recipients are electively converted at any time. As a result, we feel it is inappropriate to assume that cyclosporine conversion will be a major factor any time soon and,

therefore, subsequent year annual immunosuppressive drug costs will approximate those reported in Table 13-48.

This summarizes the major concerns we have with the cost information amassed here. There is little doubt that this information is extremely valuable and will greatly facilitate the development of projections that pertain to the Medicare Part C program. It will be necessary to revise these projections as changes occur in the administration of immunosuppressive agents, or as new agents are incorporated into the immunosuppressive armamentarium.

Discussion

Developments in transplant immunosuppression are difficult to predict, as are developments in the field of transplantation more generally. One can anticipate change, but prediction of the actual events that will transpire is almost impossible. For example, few would have predicted the dramatic impact of cyclosporine, although most people in the field felt that important changes were about to occur. Whether OKT-3 (ORTHOCLONE), FK-506, or DSG hold the same promise is unclear, even though many people in the field today would cast a negative ballot. All things considered, graft survival rates are extremely good, and the overall margin of improvement with highly specific immunosuppression may be less than expected. In short, further improvement in graft survival rates are likely to be due to factors unrelated to immunosuppression. This, of course, is likely to complicate the clinical "picture" of the future.

Given the costs associated with newer immunosuppressive agents, such as cyclosporine and ORTHOCLONE OKT-3, it is likely that greater attention will

focus on the relative cost-effectiveness of various immunosuppressive protocols, although this has not been the objective of this chapter. The most significant issue here is relatively straightforward--are the added costs associated with more costly per patient protocols cost-effective over both the short- and long-term? One factor that may favorably impact upon the cost of cyclosporine is that the patent on the product is due to expire in 1992. If other pharmaceutical firms choose to manufacture the product, it is possible that the cost of a generic cyclosporine product may be less than SANDIMMUNE. This is difficult to predict, although it is apparent that only one other major immunosuppressant used in transplantation is generically produced--prednisone. Clearly, the market for cyclosporine is small considering that its primary use is limited to organ transplantation. Annual sales of the drug in the United States, which accounts for about 50 percent of worldwide sales, reach \$100 million (Byrne, 1988:198). Sales could increase considerably if cyclosporine proves of value in the treatment of other autoimmune diseases such as juvenile onset diabetes and rheumatoid arthritis.

In conclusion, there are likely to be relatively few changes between 1988 and 1995 in transplant immunosuppression with serious consequences for the overall costs associated with organ transplantation. Donor supply is likely to increase modestly, the cost of major immunosuppressive agents is likely to rise at a pace consistent with other drugs, and graft survival rates will be similar to those observed today. With the exception of OKT-3, none of the newer immunosuppressive agents are likely to be widely adopted in the clinical setting, although experimental studies will continue with modest success. OKT-3 may be used increasingly as a prophylactic agent and,

following FDA approval, Minnesota ALG may be used more widely. While it is unlikely that cyclosporine conversion protocols will receive widespread acceptance, it is possible that concerns related to costs may engender a renewed interest in conversion protocols. Moreover, greater attention may be paid to the long-term complications associated with all immunosuppressive agents. Despite all the uncertainty, this chapter represents a careful attempt to put the costs of immunosuppression into perspective, in hopes that HCFA actuaries can plan for the future of the Medicare Part C program.

CHAPTER 14

DONOR CHARACTERISTICS

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CHAPTER 14 DONOR CHARACTERISTICS

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Introduction

In the previous chapters of this report, we examined renal transplantation from a number of different perspectives. In these analyses we focused primarily on the transplant procedure and the transplant patient. We began with an examination of the social and medical characteristics of transplant recipients, followed by a description of the transplant surgery and the immunosuppressive drug protocols following transplantation. Next, we examined a series of patient outcomes, including graft and patient survival, renal function and medical complications following transplantation, and subsequent hospitalizations. Our analysis also included an examination of employment, physical functioning, health status and subjective measures of quality of life following surgery. Finally, we focused on transplant costs--the costs of the transplant procedure, as well as the costs associated with the transplant patients' immunosuppressive drug protocol.

In this chapter we turn our attention from transplant recipients to organ donors. As described in Chapter 3, in addition to providing information on each transplant recipient, the Baseline Medical Records Data Abstraction Form was also used to obtain limited information regarding the characteristics of each organ donor. For the purpose of our analysis, we present aggregate data for all 396 organ donors included in our study. However, for many variables there is considerable variation across transplant centers. Therefore, for selected variables, we also present data separately for each of the five participating transplant centers.

Given the level of transplant activity in the United States, it is surprising how little information has historically been available on organ donors at the national level. For example, it has been difficult to obtain

data on the age, sex, and clinical characteristics of donors. Cause of death data have been available on selected donors but, for the most part, any additional data have been selectively maintained at the level of the individual transplant center or, in some instances, by large regional networks of transplant centers and procurement hospitals such as the South-eastern Organ Procurement Foundation and the New England Organ Bank (Barnes, 1983:88; Lucas et al., 1987:249; Perez et al., 1988:553 Banowsky et al., 1986:1157; Emery et al., 1986:356; Peters et al.; 1988:829). Elsewhere we have published data on the characteristics of heart donors in the United States (Evans et al., 1987:2501). Fortunately, through the formation of the United Network for Organ Sharing (UNOS)--the organization in the United States responsible for the procurement and distribution of donor organs--this situation is likely to change. Data will be available nationally on various characteristics of all organ donors throughout the United States.

The remainder of this chapter is divided into three sections. First, we describe the demographic and medical characteristics of the organ donors at the time of death. In this section we also present information concerning the drugs administered to the donor in the 24 hours prior to organ removal. The second section describes the techniques used in handling the kidney following removal from the donor. The final section presents information concerning the number of donors who were multiple organ donors, and what other organs were harvested.

Demographic and Medical Donor Characteristics

The age, sex, and racial distributions of the organ donors included in the study, overall as well as by transplant center, are presented in Table 14-1.

Table 14-1
Age, Sex, and Racial Distribution of Organ Donors, Overall and by Transplant Center
Compared with 1986 Medicare Transplant Procedures

Donor Age	University of California	Ohio State University	University of Pittsburgh	University of Texas	University of Wisconsin	1986 Medicare Transplant Procedures	
						TOTAL	Procedures
Less than 10 years (%)	7.4	1.7	5.8	5.6	3.4	4.8	5.5
10-14 years (%)	4.6	10.2	4.8	8.3	9.0	5.6	6.3
15-19 years (%)	14.8	25.4	18.3	27.8	15.7	16.4	19.3
20-24 years (%)	15.7	15.3	17.3	16.7	20.2	18.7	16.6
25-29 years (%)	5.6	13.6	12.5	8.3	11.2	10.4	11.6
30-39 years (%)	16.7	17.0	19.2	5.6	21.3	16.9	19.9
40-49 years (%)	26.9	13.6	15.4	13.9	15.7	18.7	13.0
50 or more years (%)	8.3	16.9	6.7	13.9	3.4	8.6	7.9
Donor Sex							
Male (%)	63.0	57.6	65.4	61.1	68.5	63.9	66.1
Female (%)	37.0	42.4	34.6	38.9	31.5	36.1	33.9
Donor Race							
White (%)	78.7	91.5	94.2	83.3	92.2	88.1	90.2
Black (%)	5.6	8.5	4.8	2.8	2.2	4.8	7.9
Asian (%)	3.7	0.0	0.0	0.0	2.2	1.5	0.7
Hispanic (%)	12.0	0.0	0.0	13.9	1.1	4.8	N/A
Native American (%)	0.0	0.0	1.0	0.0	0.0	0.3	0.4
Don't know (%)	0.0	0.0	0.0	0.0	2.2	0.5	N/A

* Donor characteristics are for cadaveric kidney transplant recipients, 18 years of age or older, receiving their first transplant.
source: Paul Eggers, Health Care Financing Administration, 1989.

As previous studies have shown, most organ donors are male (63.9%) and white (88.1%). Organ donors in the study ranged from 2 to 63 years of age, with the average donor age being 29.6 years (S.D.=13.6). Although most donors were between 15 and 49 years of age, 10.4% of the donors were less than 15 years old and 8.6% were 50 years of age or older. As shown in Table 14-1, with respect to age, sex, and race, the characteristics of organ donors in our study are quite similar to the characteristics of organ donors of Medicare cadaveric kidney transplant recipients (for procedures in which the transplant recipient was 18 years of age or older, receiving their first transplant).

Differences in the characteristics of donors varied considerably across transplant programs. For example, the University of California, San Francisco had higher proportions of patients in the very youngest age group (less than 10 years) and a higher proportion of patients 40 years of age or older than the other transplant centers. It is noteworthy that the University of California, San Francisco, is a very active pediatric as well as adult transplant center. In contrast, the University of Wisconsin had much lower proportions of patients in the youngest and oldest age groups. All centers had more male donors than female donors; however, the percentage of female donors was highest at Ohio State University. Racial differences, perhaps not surprisingly, reflect differences in the racial composition of the various geographical regions. Hispanic organ donors were most common at the University of Texas and the University of California. Asian donors were most common at the University of California and the University of Wisconsin. Although all centers had some Black donors, the percentage was highest at Ohio State University. Primarily because of the large proportion of Hispanic

donors, the proportion of donors who were white was lowest at the University of California and the University of Texas.

As shown in Table 14-2, organ donors generally were free from disease at the time of their death. Only 15 donors (3.8%) were reported to have had hypertension and only seven donors (1.8%) were reported to have had a malignancy at the time of death. Less than one percent were reported to have had arteriosclerosis or diabetes. The urine output of donors in the last hour before kidney removal is summarized in Table 14-3. Mean urine output in the last hour before organ removal among the donors included in the study ranged from a minimum of 30 ml to a maximum of 2800 ml. The mean urine output was 395.2 ml (S.D.=384.7).

Table 14-4 presents information regarding the drugs administered to organ donor in the 24 hours prior to kidney removal, overall as well as by transplant center. As is shown in the table, 79.3 percent of all donors in the study received vasopressors, 70.5 percent received diuretics, 62.4 percent received steroids, and 32.3 percent received antibiotics in the 24 hours prior to organ removal. However, there is considerable variation in the drugs administered across transplant programs. For example, only 61.0% of donors at Ohio State University received vasopressors in the 24 hours prior to organ removal, compared with 88.9% of donors at the University of Texas. Almost all donors at Ohio State University (94.9%) and the University of Wisconsin (95.5%) received diuretics. At the University of California, on the other hand, only 40.7% of donors received diuretics. The use of steroids was highest at Ohio State University and the University of Texas. While overall 32.3% of donors received antibiotics in the 24 hours prior to kidney removal,

Table 14-2
Comorbid Conditions of Donor at Time of Death

<u>Condition</u>	<u>Number of Donors</u>	<u>Percent of Donors</u>
Hypertension	15	3.8
Arteriosclerosis	3	0.8
Diabetes	2	0.5
Malignancy	7	1.8
Sepsis	0	0.0

Table 14-3
Urine Output of Donor in the Last Hour Before Kidney Removal

<u>Number of ml</u>	<u>Number of Donors</u>	<u>Percent of Donors</u>
Less than 100	23	5.8
100 - 199	108	27.3
200 - 299	86	21.7
300 - 399	44	11.1
400 - 499	33	8.3
500 - 999	64	16.2
1000 or more	35	8.8
Don't Know	3	0.8

Range = 30.0 - 2800.0

Mean = 395.2

S.D. = 384.7

Table 14-4
Drugs Administered to Organ Donors in the 24 Hours Prior to Removal
of the Kidney, Overall and by Transplant Center

	University of California	Ohio State University	University of Pittsburgh	University of Texas	University of Wisconsin	TOTAL
Vasopressors (%)	84.3	61.0	78.8	88.9	82.0	79.3
Diuretics (%)	40.7	94.9	69.2	61.1	95.5	70.5
Steroids (%)	43.5	84.7	64.4	94.4	55.1	62.4
Antibiotics (%)	38.0	11.9	43.3	5.6	37.1	32.3

only 5.6% of donors at the University of Texas and 11.9% of Ohio State University donors received antibiotics.

According to medical records, the number of renal arteries present in the donor kidney was as follows: 75.0 percent had one artery; 21.5 percent had two arteries; 2.5 percent had three arteries; 0.3 percent had four arteries; 0.3 percent had five arteries; and 0.5 percent provided no information. Of the 396 donor kidneys, 14 (3.5%) were reported to have been injured at the time of organ removal.

Organ Preservation

The medical and surgical records were examined to determine the warm time, cold time, and total pulsatile perfusion time for each of the 396 patients included in the study. The warm ischemia times reported for all patients are summarized in Table 14-5. Among the patients included in the study, warm ischemia time ranged from 0 to 46 minutes. Almost two-thirds (63.1%) had reported warm ischemia times of less than 10 minutes. Only 5.0 percent had reported warm ischemia times of 40 or more minutes.

Organ preservation techniques varied from one transplant center to another. As a result we have chosen to report cold time and total pulsatile perfusion time separately for each of the five participating transplant centers (see Table 14-6). Among the 396 transplant procedures performed in the study, cold time ranged from 0 to 51 hours, with almost one-half (49.7%) reporting a cold time of 0 hours. Similarly, total pulsatile perfusion time ranged from a minimum of 0 hours to a maximum of 61.25 hours, with 35.1 percent reporting a total pulsatile perfusion time of 0 hours. However, of much more interest than overall differences are the differences in the

Table 14-5
Warm Ischemia Time

<u>Length of Time (In Minutes)</u>	<u>Number of Patients</u>	<u>Percent of Patients</u>
0 - 9.99	250	63.1
10 - 14.99	12	3.0
15 - 19.99	32	8.1
20 - 24.99	29	7.3
25 - 29.99	23	5.8
30 - 39.99	30	7.6
40 or more	20	5.0

Range = 0 - 46
Mean = 9.58
S.D. = 13.37

Table 14-6
Cold Time and Total Pulsatile Perfusion Time, Overall and by Transplant Center

	University of California	Ohio State University	University of Pittsburgh	University of Texas	University of Wisconsin	TOTAL
Cold Time						
0 hours (%)	98.1	1.7	0.0	2.8	100.0	49.7
0.1 - 4.9 hours (%)	0.0	88.1	1.0	8.3	0.0	14.1
5.0 - 9.9 hours (%)	0.9	0.0	5.8	13.9	0.0	3.0
10.0 - 19.9 hours (%)	0.9	5.1	18.3	47.2	0.0	10.1
20.0 - 29.9 hours (%)	0.0	5.1	40.4	27.8	0.0	13.9
30.0 - 39.9 hours (%)	0.0	0.0	19.2	0.0	0.0	5.1
40.0 or more hours (%)	0.0	0.0	15.4	0.0	0.0	4.0
Total Pulsatile Perfusion Time						
0 hours (%)	0.0	0.0	99.0	100.0	0.0	35.1
5.0 - 9.9 hours (%)	0.0	1.7	0.0	0.0	0.0	0.3
10.0 - 19.9 hours (%)	1.9	61.0	0.0	0.0	3.4	10.4
20.0 - 29.9 hours (%)	14.8	28.8	0.0	0.0	46.1	18.7
30.0 - 39.9 hours (%)	34.3	6.8	0.0	0.0	34.8	18.2
40.0 or more hours (%)	49.1	1.7	1.0	0.0	15.7	17.4

preservation techniques used by the various transplant centers. As is clearly shown in Table 14-6, three of the transplant programs--the University of California, Ohio State University, and the University of Wisconsin--perfuse their kidneys. The University of Pittsburgh and the University of Texas, on the other hand, use cold storage.

Other Organs Harvested

Finally, information was obtained regarding whether or not the kidney donors were multiple organ donors and, if so, what other organs or tissues were removed for transplantation. This information, overall and by transplant center, is summarized in Table 14-7. Based on available information, 63.6 percent of the kidney donors were multiple organ donors, while 28.3 percent were not. Information was not available for 8.1 percent of the organ donors included in the study. Of the 396 kidney donors, 41.9 percent also donated corneas, 38.9 percent donated hearts, 17.7 percent donated livers, and 14.4 percent donated bone. Only 11.4 percent were pancreas donors and even fewer donated skin (4.8%) and lungs (2.3%).

Again, what is perhaps most interesting, is the variation in multiple organ donation across transplant centers. Over 80 percent of the 36 kidney donors at the University of Texas and almost 90 percent of the 108 kidney donors at the University of California were multiple organ donors. In contrast, only 39 percent of the 59 kidney donors at Ohio State University were multiple organ donors (although information was not available for 6.8 percent of the donors).

Perhaps not surprisingly, there is also considerable variation in the specific organs donated by transplant center. In many cases, the differences

Table 14-7
Multiple Organ Donation, Overall and by Transplant Center

	University of California	Ohio State University	University of Pittsburgh	University of Texas	University of Wisconsin	TOTAL
Multiple Organ Donor						
Yes (%)	89.8	39.0	46.2	80.6	61.8	63.6
No (%)	10.2	54.2	26.9	19.4	38.2	28.3
Don't Know (%)	0.0	6.8	26.9	0.0	0.0	8.1
Other Organs Donated						
Heart (%)	72.2	16.9	28.8	38.9	24.7	38.9
Liver (%)	12.0	3.4	26.9	22.2	21.3	17.7
Lungs (%)	1.9	0.0	4.8	5.6	0.0	2.3
Pancreas (%)	3.7	5.1	4.8	13.9	31.5	11.4
Corneas (%)	73.1	32.2	18.3	50.0	34.8	41.9
Skin (%)	5.6	0.0	0.0	36.1	0.0	4.8
Bone (%)	37.0	0.0	3.8	36.1	0.0	14.4
Other (%)	0.0	8.5	0.0	19.4	0.0	3.0

reflect the presence of an extrarenal transplant program in the same geographic area. For example, an impressive 72.2 percent of the 108 kidney donors at the University of California, San Francisco were also heart donors. This is not particularly surprising, however, given the proximity of the Stanford heart transplant program. Similarly, 26.9 percent of the 104 kidney donors at the University of Pittsburgh donated livers and 31.5 percent of the 89 kidney donors at the University of Wisconsin were pancreas donors, no doubt related to the presence of liver and pancreas transplant programs at these same institutions.

While some of the variation in the specific organs and tissues harvested may reflect the geographic location of major transplant programs, our data seem to suggest that some organ procurement programs are more effective than others in the procurement of tissues and extrarenal organs. While overall 41.9 percent of organ donors also donated corneas, the percentages ranged from 73.1 percent at the University of California to 18.3 percent at the University of Pittsburgh (it should be recognized, however, that information was not available for 26.9 percent of the kidney donors at the University of Pittsburgh). A large variation in the procurement of bone is also evident. While none of the kidney donors at Ohio State University or the University of Wisconsin donated bone, over one-third of the kidney donors at the University of California (37%) and the University of Texas (36.1%) also were bone donors.

There has been some speculation that multiorgan procurements have negatively affected kidney procurement rates. For example, anecdotal reports from some quarters, have suggested that kidneys have become nonviable during the procurement of extrarenal organs. At this time, however, there is

little empirical evidence to support this claim and it is conceivable that this change has been leveled by those surgeons who have been less than enthusiastic about multiple organ retrieval. In short, some surgeons remain reluctant to become involved in multiorgan harvest because of past misadventures where organs have become nonviable due to the extended period of time required for multiorgan retrievals. As this process has become more routine, however, these claims are made much less frequently today.

The problem has eased somewhat, however, with the considerable increase in the number of heart transplant programs in the United States. Through the United Network for Organ Sharing (UNOS) there is far greater potential than previously existed to move organs throughout the United States.

Despite the foregoing, it nonetheless remains unlikely that every donor will serve as a source of multiple organs and tissues, although at least theoretically this need not be the case (Bradley *et al.*, 1988:846). With regards to this point, data from the National Heart Transplantation Study (NHTS) are particularly relevant (Evans *et al.*, 1987:2501). In the NHTS, the majority (87%) of all heart donors were multiple organ and tissue donors. Of the donors, 99.1 percent were a source of kidneys, 26.6 percent corneas, 6.7 percent livers, 4.7 percent pancreas, and 0.9 percent skin. Clearly, there is significant potential for multiple organ and tissue procurement.

CHAPTER 15

UNITED STATES PUBLIC OPINION CONCERNING THE PROCUREMENT AND DISTRIBUTION OF DONOR ORGANS

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CHAPTER 15 UNITED STATES PUBLIC OPINION CONCERNING THE PROCUREMENT AND DISTRIBUTION OF DONOR ORGANS

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Introduction

Over the past several years, numerous surveys have been conducted to gauge public opinion and awareness concerning organ transplantation and donation (Manninen and Evans, 1985:3111; American Council on Transplantation, 1985; Evans and Manninen, 1987). These surveys have generally shown that the public is both aware of and supportive of transplantation (Blendon and Altman, 1984:613). However, people remain uncertain as to the merits of organ donation. In fact, they are clearly less willing to have their own organs donated than they are the organs of their brain-dead relatives (Evans and Manninen, 1987). In the last year, another, perhaps more significant, policy issue was forced upon the transplant community by the media. The process and criteria by which donor organs are distributed to transplant candidates came under severe criticism (Office of the Inspector General, 1986; Office of the Inspector General, 1987). In particular, there were media reports indicating the foreign nationals or nonimmigrant aliens were being given priority for transplants over United States citizens (Office of the Inspector General, 1986). This particular issue became one of the most pressing the United Network for Organ Sharing (UNOS) (Richmond, VA) had to face shortly after its formation under government contract in October 1986.

This paper will present the results of a public opinion survey conducted by the Battelle Human Affairs Research Centers (commissioned by UNOS) to provide information needed to formulate UNOS policies with respect to the procurement and distribution of donor organs (Evans and Manninen, 1987). UNOS policies were initially drafted by the Foreign Relations Committee. On August 10, 1987, these draft policies were approved by the UNOS Board of

Directors. Given their importance to the international transplant community, this paper will conclude with an explicit statement of the UNOS policies governing the transplantation of nonimmigrant aliens.

Materials and Methods

Data for this study were obtained by a telephone survey of a national probability sample of 2,051 respondents (1,022 men and 1,029 women) 18 years of age and older (Evans and Manninen, 1987). The survey interviews were conducted during January 1987. Respondents were asked an extensive series of questions on a variety of topics including: (1) knowledge and awareness about organ transplantation and organ donation; (2) media coverage of organ transplantation, (3) transplant patient selection criteria, (4) general attitudes toward donor organ distribution; (5) attitudes toward nonimmigrant aliens or foreign nationals receiving transplants; (6) specific patient selection criteria; (7) who should decide who gets organ transplants; and (8) public concern about the local, national, and international distribution of donor organs. In addition, information was obtained on respondents with respect to age, sex, race, political party affiliation, marital status, size and age composition of their household, education, employment status, occupation, income, ethnic origin, attitudes toward foreign people residing in the United States, and attitudes toward the general concept of a societal "right" to health care.

It is noteworthy that the sample design for the study permits the results of the survey to be generalized to the population of the United States. This is essentially the goal of a probability sample as opposed to other statistical designs such as a quota sample or convenience sample.

Results

As shown in Table 15-1, over the past several years people have become increasingly aware of organ transplantation. More people have received information on organ donation than ever before and are carrying donor cards in growing numbers (Evans and Manninen, 1987). Most surprisingly, nearly two percent of the population indicates that it has actually been involved in the organ donation process.

The media, as suggested previously, have been very actively involved in reporting on transplant issues. The reports have been both favorable and unfavorable. Given this media attention, we sought to investigate their possible negative impact upon public perceptions of organ transplantation. We asked people to identify, without benefit of an issues list, the content of any news reports about organ transplantation that they read or heard that angered them. We found people were most likely to be angered by the following, in descending order of importance: the buying and selling of organs, the use of animals for organs, the inability of people to pay for transplants, babies getting transplants, people getting more than one transplant, and, surprisingly, too much media attention on transplantation. However, overall, the magnitude of public anger was minimal--only 16 percent of the population indicated an angry response to any news report concerning transplantation.

The distribution of donor organs has been, perhaps, the most hotly debated issue in both the print and visual media (Office of the Inspector General, 1986; Hearings before the Subcommittee on Investigations and Oversight of the Committee on Science and Technology, 1984; Council of the Transplantation Society, 1985). As mentioned, it has been contended that

Table 15-1

Responses to the Same or Similar Questions
in Three Separate Organ Transplantation/Donation Surveys

<u>Question Item</u>	<u>Year of Public Opinion Survey</u>		
	<u>1983¹</u>	<u>1984²</u>	<u>1987³</u>
Awareness of transplantation	94.0%	93.0%	98.7%
Received information on donation	69.1%	--	84.1%
Willingness to donate own organs	50.0%	45.0%	49.3%
Willingness to donate relative's organs	53.0%	85.0%	62.5%
Carry organ donor card	19.2%	17.0%	24.6%
Approached about organ donation	--	14.0%	14.9%
Given consent for organ donation	--	--	1.7%

¹ Manninen and Evans, 1985:3111.

² American Council on Transplantation, 1985.

³ Evans and Manninen, 1987.

foreign nationals have received transplants ahead of United States citizens and that normally accepted medical criteria for choosing transplant candidates have been ignored. The results of our survey, however, indicate that citizenship is not a foremost concern of the general public. In fact, over 88 percent of the people were most concerned that organs be distributed fairly and equally. Moreover, 81.4 percent of the respondents believed that "medical need, not social or economic factors, should be the only criterion used to select transplant recipients."

Over 98 percent of the respondents to our survey were citizens of the United States, and the majority (93.8%) had lived in the United States all of their lives. Despite these findings, people do not object strongly to non-United States citizens receiving transplants, even with the severe donor shortage that currently exists. About half the population does not feel that citizenship should be a consideration in deciding who gets transplanted, and another 8.4 percent did not have an opinion on the matter. In general, we found that people who reject citizenship as a distributional criterion were younger, lived in the urban fringe (as opposed to central cities or nonurbanized areas), and tended to live in the New England, Middle Atlantic, and Pacific regions.

Country of origin is a relevant consideration in the distribution of donor organs, as revealed by our survey results. In other words, members of the general public believe it is inappropriate to transplant individuals from certain countries, as shown in Table 15-2. People from Iran were clearly most likely to be subject to discrimination, and Canadians the least likely. Despite these findings, what should be kept in mind, however, is the fact that 78 percent of the population is unwilling to deny people an organ transplant on the basis

Table 15-2

Country of Origin and Denial of Organ Transplants
on Behalf of the United States Public

<u>Country</u>	<u>Percent of Respondents</u>	<u>Number of Respondents</u>
Iran	21.8	448
Cuba	16.2	332
Soviet Union	15.7	322
West Germany	9.4	192
Mexico	8.5	175
England	6.5	133
Canada	4.0	83

of country of origin. Those respondents who were more likely to deny transplants to people from other countries tended to be older and white. Females and respondents of non-Hispanic origins were somewhat more likely to deny transplants to people from certain countries. Those least likely to deny people an organ transplant on the basis of country of origin are college-educated, live in the urban fringe, and consider themselves to be independent or members of "other" political parties. Regional differences were also observed.

Based on the foregoing, what we can conclude, therefore, is that there is no clearcut mandate to exclude nonimmigrant aliens from transplantation. Media reports have erroneously suggested otherwise. It is, of course, important to recognize that the issue of the transplantation of nonimmigrant aliens raises economic concerns as well. The position of the Health Care Financing Administration has been that it does not want to pay the acquisition costs for non-Medicare kidney transplant recipients (Eggers, Health Care Financing Administration, 1989). Also, the Office of the Inspector General appears to have taken a position that is at variance with public opinion (Office of the Inspector General, 1986). Nonetheless, we do acknowledge that about half the population supports a discriminatory policy based on country of origin and that people differ in their views according to country of origin.

During its deliberations, the National Task Force on Organ Transplantation considered a number of approaches to address the foreign national or nonimmigrant alien issue (National Task Force on Organ Transplantation, 1986). While recognizing that the problem would be best solved if all countries could make transplantation available within their

geographical borders, it was clear that many countries were simply incapable of doing so any time in the near future. Out of primarily a humanitarian concern, the Task Force adopted a quota system for kidney transplants and an exclusionary policy with respect to extrarenal transplants, unless a suitable United States citizen recipient could not be identified for transplantation.

In consideration of this recommendation that temporarily favored a quota system, a question was included in our survey to permit an assessment of public opinion towards such a policy. Respondents were again made aware of the discrepancy between the need for donor organs and their availability, and then asked how they felt about a quota policy. Only 8.5 percent of the respondents found such a policy acceptable. About 50 percent felt that quota policies were bad and that "... whoever needs a transplant should be able to get it." Finally, 32.6 percent of the respondents said that a quota system constituted "... a bad policy. Only United States citizens should get transplants." Approximately 9.0 percent of respondents did not answer the question.

Finally, we also studied the attitudes of people towards the regional distribution of donor organs. In particular, questions have been raised about the shipment of organs outside the United States (Office of the Inspector General, 1986). In this regard, a sense of altruism on behalf of the American public prevails. Over 86 percent of the United States population feels that if no suitable recipient can be identified in the United States, then it is acceptable to ship an organ to a foreign country where another patient from that country may benefit from a transplant operation. Younger respondents, more highly educated respondents, those with high incomes, and those who

regard themselves as politically independent were more likely to agree with this policy.

Discussion

The results of this survey indicate that the media were presumptuous in their implication that United States citizens should be granted priority status over nonimmigrant aliens in the provision of transplantation services. The population is almost evenly divided on this particular issue (Kleinig, 1986:24; Jonasson, 1986:25; Prottas, 1986:23). Not surprisingly, the public seems most concerned about the application of social and economic criteria in the selection of transplant recipients. Medical need and successful outcome were found to be two of the most significant factors determining who should receive a transplant. These views are consistent with the prevailing clinical orientation that characterizes medicine today.

Despite the foregoing, nearly one third of the population objects to foreigners coming to the United States for the sole purpose of getting a transplant, although people were less inclined to reject nonimmigrant aliens for transplantation provided they lived and worked in the United States. Moreover, nearly 50 percent of the people surveyed did not feel citizenship should be a consideration in deciding who receives a transplant.

Given these findings, and after extended deliberations, the UNOS Foreign Relations Committee drafted policies with respect to the transplantation of foreign nationals. These policies, as approved by the Board on August 10, 1987, are summarized below:

1. Selection of patients for transplantation shall be based on waiting time and on medical and scientific criteria that are publicly stated and fairly and uniformly applied.

2. Selection of patients for transplantation shall not be subject to favoritism or based on political influence, discrimination on the basis of race, or sex, or financial advantage.

In addition, the Board approved specific guidelines for any transplant center allowing nonresident aliens on their waiting list. These guidelines are as follows:

1. Transplantation of nonresident aliens is a humanitarian act and shall not be performed for financial advantage. Transplant centers accepting nonresident aliens onto their waiting list shall charge the same fees for service as charged to domestic patients, although it is recognized that actual reimbursement for charges may differ according to payment source. Medicare, Medicaid, and other government funding intended for support of domestic patients shall not be used for services to nonresident aliens.
2. UNOS members shall not enter into contractual arrangements with foreign agencies or governments for the transplantation of nonresident aliens. Patient referrals shall be on a case-by-case and physician-to-physician basis.
3. Transplantation of nonresident aliens shall in general only be performed in transplant centers with well-established, historical patterns of international referral and reputation for both the treatment of primary and end-stage organ disease and corresponding transplantation of the particular organ. A training program in organ transplantation that includes the training of physicians from underserved nations and a record of participation in educational programs aimed at the development of transplantation services in these nations is desirable.
4. UNOS member centers that accept nonresident aliens on their waiting lists should establish a mechanism for community participation and review.
5. All patients accepted onto the transplant waiting list must be selected to receive organs in accordance with the policies for equitable allocation as mandated by the Board of Directors of UNOS.

A policy was also established for the audit of transplant centers where nonresident aliens are accepted on the waiting list. This policy is as follows:

All UNOS member transplant centers will agree, as a condition of membership, to allow the UNOS Committee on Foreign Relations to review and audit all center activities with regard to the transplantation of nonresident aliens at the discretion of the Committee. The Committee will review the activities of all member transplant centers whose proportion of nonresident alien recipients for any solid organ transplant exceeds the 10% guidelines of the National Task Force to determine the circumstances upon which this activity has continued.

Finally, policies were formulated for both the exportation and importation of organs. The exportation of organs from, and the importation of organs into, the United States is prohibited except when distribution is arranged and coordinated by UNOS. In addition, the Board has imposed the following requirements:

1. Exportation of organs from the United States (excluding Canada) shall be prohibited unless a well-documented and verifiable effort, coordinated through UNOS, has failed to find a suitable recipient for that organ in the United States or Canada.
2. UNOS members shall not bill or receive from the Health Care Financing Administration the acquisition or any other processing or shipping costs for any organ that is exported outside the United States. Such costs must be paid by the recipient of the foreign agency which agrees to accept the organ.

The foregoing constitutes UNOS policies with respect to the transplantation of foreign nationals. They are the outcome of extensive deliberations that took place over a 1-year period. Every attempt was made to resolve conflicting views and to overcome adverse media reports that were, at times, contrary to the public opinion data amassed in the survey reported here. Nonetheless, the policies reviewed here will undoubtedly hold in check any impropriety. Also, the UNOS Board recognizes that these policies are subject to change as time and experience may dictate.

Acknowledgement

The following people serve on the UNOS Foreign Relations Committee and were instrumental in the development of UNOS policies with respect to the transplantation of foreign nationals: Robert D. Gordon, M.D. (Chair), Charles Carter, M.D., James Childress, Ph.D., Frances L. Delmonico, M.D., Roger W. Evans, Ph.D., Neal Glass, M.D., Jack Hussey, M.D., Anita Principe, John A. Robertson, J.D., Fred Sanfillippo, M.D., Charles Van Buren, M.D., and Gene Pierce (ex officio).

CHAPTER 16

**MONEY MATTERS: SHOULD ABILITY TO PAY EVER BE A CONSIDERATION
IN GAINING ACCESS TO TRANSPLANTATION?**

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CHAPTER 16 MONEY MATTERS: SHOULD ABILITY TO PAY EVER BE A CONSIDERATION IN GAINING ACCESS TO TRANSPLANTATION?

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Introduction

Most of us have puzzled from time to time over the complex issues associated with the payment of organ transplantation procedures and the routine care required by patients following a successful transplant. We have all been exposed to various commentaries suggesting that organ transplants are too expensive given other health care needs (Englehardt, 1984:66; Baily, 1988:198; Welch and Larson, 1988:171). In addition, we have been entertained by, or been a part of, debates concerning the experimental or therapeutic status of various organ transplant procedures (Evans, 1986:91).

In each of the foregoing instances, we can all agree there are clear problems; the solutions to these problems, however, are elusive. While one can discuss at great length the "economics of transplantation," it is beyond the scope of this chapter to address each of the issues to which we have alluded here (Evans, 1985:129; 1986:603; 1987:63; 1987:61). This has been done elsewhere from both the specific context of transplantation and the general context of health care policy (Evans, 1986:91; 1986:425). This chapter will focus on a single question, should the ability to pay be a condition for gaining access to transplantation?

To address this question, we will begin by discussing the general problems of both the medically uninsured and the medically underinsured. This discussion will provide us with an important baseline to evaluate the specific problems of potential transplant recipients. In this regard, the recommendations of the National Task Force on Organ Transplantation will be highlighted.

We will next consider the relationship between insurance coverage policy and medical innovation. Increasingly restrictive coverage policies, such as

those to which organ transplant recipients have been exposed, could potentially restrict major medical innovations. This is not, however, the fault of insurers who simply reflect what employers and subscribers are willing to underwrite through higher insurance premiums, copayments, and deductibles.

The actual coverage of specific organ transplants, has been, and continues to be, difficult to follow. Periodic surveys of insurers have been conducted, although the frequency of these in recent years has declined. Related to coverage is reimbursement and, in a short section, we indicate how the selection of a reimbursement methodology may restrict patient access to transplantation.

Next, we review the "conditions of access" to transplantation, based on public opinion poll data. In general, people believe there are very few worthy social criteria for the selection of transplant recipients. People believe that medical criteria should be the primary determinants of patient selection. Public opinion data suggest that people might be willing to pay additional premiums, and possibly taxes, to cover the costs associated with transplants, but their actual willingness to do so remains unmeasured.

Finally, the chapter concludes with a few thoughts regarding the worthiness of an ability to pay criterion in the selection of transplant recipients. While such a criterion may be morally reprehensible, it is important to recognize that there are very real limits to how successfully we can assure all people equal access to transplantation. The conclusion is simple: while ability to pay should not limit access to transplantation, it is evident that it currently is and, moreover, will continue to be a limitation that disproportionately impacts upon the poor and minorities.

The Health Insurance Dilemma

Today it is estimated that between 31.0 and 37.0 million people in the United States are uninsured (Iglehart, 1982:836; 1985:59; Wilensky, 1988:133; Blendon, 1988:3176; Laudicina, 1988:97; Thorpe, 1988:344; Short et al., 1988; Editorial, 1988:316). As shown in Table 16-1, this figure has varied from survey-to-survey and time period-to-time period. The most recent figure of 37.0 million is based on the 1987 National Medical Expenditure Survey (NMES) (Short et al., 1988). Thus, the uninsured represent 15.5 percent of the population in 1987, up from 12.3 percent of the population uninsured at the first interview of the National Medical Care Expenditures Survey a decade ago (Walden et al., 1985). The NMES data confirms and updates a number of well-known facts about this population. Lack of insurance is observed at the highest rate among young adults and among blacks and Hispanics, as well as persons in families where no one is employed. However, workers and their families still account for more than three-quarters of the uninsured (Short et al., 1988; Aday et al., 1984).

The lack of insurance is only one aspect of a very complicated dilemma. Add to this another 26.0 or 27.0 million people who are underinsured. All total, therefore, as many as 64.0 million people are uninsured or underinsured. When coverage of transplant procedures is a consideration, both the uninsured and the underinsured are at near equal risk of not gaining access to selected transplant procedures based on an ability to pay criterion. And, as these figures suggest, the problem is by no means small. In short, at least 26.1 percent of the United States population is at risk of not having insurance coverage for a liver or heart transplant; kidneys, of course, are covered for

Table 16-1
Total Uninsured Population, Recent Estimates

<u>Survey</u>	<u>Date</u>	<u>Number (Millions)</u>	<u>Percent of Population</u>
SIPP	3rd quarter, 1985	31.8	15.2%
SIPP	4th quarter, 1985	31.3	14.9
CPS	March, 1986	37.0	17.0
CPS	March, 1986	34.8	14.8
HIS	1986	30.8	14.8

NOTES: SIPP = Survey of Income and Program Participation
CPS = Current Population Survey
HIS = Health Interview Survey

SOURCE: Wilensky, 1988:133.

over 90.0 percent of all United States' citizens under provisions of Medicare's End-Stage Renal Disease Program. Moreover, what is equally disconcerting is the fact that the financially disadvantaged and minorities are at great risk of not having the insurance or the resources required to cover the costs of an extrarenal transplant, should one be required.

To understand the potential ramifications of being uninsured or underinsured, consider that the majority of transplant programs in the United States today require assurance of payment for transplantation, often taking the form of a direct down payment prior to transplant or, alternatively, prior approval by the patient's public or private insurer. Because of previous misadventures, hospitals recognize that significant losses are incurred when payment has not been properly assured. These losses are not easily recovered, and become even more troublesome in instances where the charges associated with the transplant exceed the amount agreed upon by the patient, his or her family, the insurer, and the transplant hospital. Requiring patients to provide actual payment or assurance of payment prior to transplant underscores the fact that Caplan's "green screen" is operational--in principle, a patient who is able to pay is more likely to get a transplant than one who is not (Caplan, 1987:10).

From the patient's perspective, the ability to pay "factor" is seemingly unfair. Why should an individual in need of accepted medical care be denied that care based on their ability to pay? However, the transplant hospital also has a justifiable claim--its economic losses are significant if transplants are provided at no charge to medically needy, although financially indigent, recipients. To recover losses associated with unreimbursed transplants, hospitals are forced to increase their charges to other patients, thus giving

rise to higher hospital operating costs which, in turn, ultimately threaten the viability of the hospital in an increasingly competitive marketplace. Clearly, both the patient and the transplant hospital have legitimate claims, claims that often cast the insurance industry in a negative light. For example, providers and patients have bitterly chastised both public and private insurers for failing to pay for all transplants (Health Insurance Association of America, 1985; Kastriel, 1985). Being a conservative industry, insurers often claim that costly procedures with limited application are experimental and must await further evaluation until a consensus can be reached within the clinical community (Towery and Perry, 1981:59; Finkelstein et al., 1984:89; Ruby et al., 1985:141). This process will be further described below.

Given the availability of adequate public or private insurance, or personal wealth, it is apparent that neither the patient nor the hospital would have a problem. The well-insured patient, or the patient who has considerable personal wealth, is a source of little grief to transplant hospitals because of their ability to pay for the medical care they require. Such patients are readily accepted as transplant candidates. For the time being, in the absence of socialized medicine, the aforementioned ideal world cannot be achieved and, as a result, ability to pay will continue to play a significant role in patient access to transplants. In fact, it is likely that in the immediate future, ability to pay will play an increasingly important role. What should be recognized, however, is that ability to pay is a condition of access that characterizes all of medical care in a health care delivery system such as ours (Aday et al., 1984). Transplantation is simply a specific example, more poignant only because of the immediacy of the life and death crisis. This, of course, is not to suggest that we ignore the problem because of its

near trivial magnitude, but only that we understand that to solve the particular problem, we must address the general issue.

Several years ago the National Task Force on Organ Transplantation made a very significant effort to address the economic problems associated with transplantation. In its initial report, the Task Force investigated problems transplant recipients encountered in gaining access to costly immunosuppressive drugs (Task Force on Organ Transplantation, 1985). It was determined that approximately 25 percent of the transplant population had no private insurance coverage for immunosuppressive medications or coverage by a State Medicaid program or other State program (Task Force on Organ Transplantation, 1985). In response to this dilemma, the Task Force recommended that "...any Federal funding for immunosuppressive medications should be limited to assisting only financially needy Medicare-eligible transplant patients." As a mechanism of response, the Task Force recommended "... the establishment of a joint Health Care Financing Administration-Public Health Service program to provide immunosuppressive medications to transplant centers for distribution to financially needy Medicare-eligible transplant patients." The proposed program was to be administered by the Public Health Service and supported by Medicare Trust Funds. At the time, this was considered a bold step and, indeed, it was.

Ultimately the recommendations of the Task Force were legislatively side-stepped, but the problem of access was resolved temporarily within a few months, and more permanently in June, 1988 when Congress passed the Medicare Catastrophic Coverage Act. Today, our research shows that over 90 percent of kidney transplant recipients have third-party assistance in order to meet the expenses associated with immunosuppressive drugs (see Chapter 8).

The second access issue the Task Force addressed concerned coverage of the actual costs incurred for the transplant procedure itself (National Task Force on Organ Transplantation, 1986). The problems here were considerably more complex, and the societal costs far greater. Moreover, there was no way to avoid the general issue of the medically uninsured. Crafting a solution to this problem, although a part of the Task Force mandate, was well beyond the time and resources available in 1985-86.

In addressing the equitable access to transplantation issue, the Task Force concluded that patient financial status should not limit the availability of transplantation (National Task Force on Organ Transplantation, 1986). It was felt that all transplant procedures recognized as medically effective should be made available through reimbursement by existing public and private insurers. Additionally, it was determined that the federal government should develop reimbursement mechanisms for the care of patients who have no other source of funds. Various recommendations are contained within the Task Force final report regarding access to transplantation and ability to pay.

These are as follows:

- Selection of patients for transplants should not be subject to favoritism, discrimination on the basis of race or sex, or ability to pay.
- In order to insure that patients in need of an extrarenal organ transplant can obtain procedures regardless of ability to pay, the Task Force recommends that private and public health benefit programs, including Medicare and Medicaid, should cover heart and liver transplants, including outpatient immunosuppressive therapy that is an essential part of posttransplant care.
- A public program should be set up to cover the costs of people who are medically eligible for organ transplants but who are not covered by private insurance, Medicare, or Medicaid and who are unable to obtain an organ transplant due to lack of funds.

To be sure, these were very significant recommendations, recommendations

that are often contrasted with those of the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research which stated that ". . . equitable access to health care requires that all citizens be able to secure an adequate level of health care without excessive burdens." (Presidential Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, 1983). In response to this, the Task Force concluded that:

Although opinions may differ over what constitutes an "adequate level of care" and "excessive burdens," life-saving procedures that are comparable in cost and efficiency to other procedures that are routinely funded would seem to qualify.

Thus, at every juncture, the Task Force rejected the notion that ability to pay should obstruct access to transplantation.

While continuing to support the remarkable findings, conclusions, and recommendations of the Task Force, we must be cognizant of the full implications of the recommendations. It is important to recognize the concerns of both public and private insurers, as well as legislators, who must respond to sweeping recommendations that clearly go beyond the provision of transplantation services (Health Insurance Association of America, 1985; Schaffarzick, 1987:84; Bunker *et al.*, 1982:687). Moreover, the problems that insurers and legislators face are essentially problems that we as a society must face--the essence of which can be captured by a single question: what is the value of a human life (Evans, 1987:61)? Coupled with this are concerns related to innovation in medical care, the core of which can, again, be characterized by a single question: should the development of a new innovation be made responsive to financial constraints when it is evident that the new innovation will be costly and potentially inaccessible to a large segment of the population (Greenberg and Derzon, 1981:967; Bunker *et al.*,

1982:620; Tanneberger, 1988:113; Nazametz, 1987:12)? Where these questions meet, we have the essential interlocking of ethics and science.

Coverage Policy and Medical Innovation

Organ transplantation ranks among the most significant of medical innovations in the past twenty years (Cerilli, 1987; Mathieu, 1988; Groth, 1988; Maddrey, 1988). Without considerable research support, surgical stamina, and medical management skills, it is unlikely that transplant surgery would have taken a worthy place in the clinical armamentarium to treat a variety of end-stage diseases. However, as scientific advancements yield medical progress, payment becomes essential to clinical introduction and therapeutic patient management. Where primary research terminates, clinical applications take over (McKinlay, 1981:374; Read and Campbell, 1988:174; Chalmers, 1988:1228). Basic research gradually takes a back seat to clinical research. Initially, what qualifies as patient treatment is indistinguishable from clinical research. Insurers who are primarily concerned with the treatment of patients, are only moderately responsive to the needs of researchers. In short, insurers, private as well as public, are not in the business of funding either basic or clinical research. Consequently, as new innovations occur, insurers make a careful evaluation in hopes of determining when an innovation has become sufficiently acceptable to qualify as treatment. Hence, the distinction between experimental procedures and therapeutic treatment.

Below we examine the development of coverage policies by insurers. This is done to introduce the concept that access to treatment may be a function of insurer coverage policies as well as the lack of insurance. In

other words, some people may be denied access to transplantation, because they have neither insurance, nor the ability to pay out-of-pocket. Other patients may be denied access to transplantation, even though they have insurance, because their insurer does not cover transplant procedures. Such persons could be considered underinsured if the majority of insurers offer coverage for the procedure in question.

Insurers typically distinguish between two concepts--coverage and reimbursement. Coverage refers to what insurers are willing to pay for, while reimbursement refers to the amount they are willing to pay for a service (Schaeffer, 1982; Office of Technology Assessment, 1984; Greenberg and Derzon, 1981:967). The development of coverage and reimbursement policy by public and private insurers for heart transplantation has been discussed at length elsewhere (Evans, 1986:425).

Here we will only highlight selected aspects of this earlier work to demonstrate that the procedures that insurers follow to develop their policies are far from arbitrary. In fact, insurers frequently have legitimate concerns that are often ignored by patients and providers who feel they have been unjustly treated by health insurers whether the insurer is private or public (i.e. Medicaid, Medicare, CHAMPUS).

In deciding what they are willing to cover, insurers have historically searched for sufficient data and sought professional opinion to answer three questions concerning new medical and surgical procedures. These questions are as follows:

- Is the procedure safe?
- Is the procedure effective?
- Does the procedure have widespread acceptance within the medical community?

These questions are not unambiguously answered. Add to these the four additional contemporary questions listed below.

- What does the procedure cost?
- Does the procedure maintain or improve the health status of the patient in the most cost-effective manner?
- Does the procedure replace an older, less efficient procedure?
- Will costs decrease as the procedure becomes more routine?

Lengthy deliberations are required to gain a consensus on the answers to these questions and, until these questions are answered satisfactorily, insurers may deny coverage, arguing that a procedure is, in their opinion, experimental and not subject to reimbursement if provided.

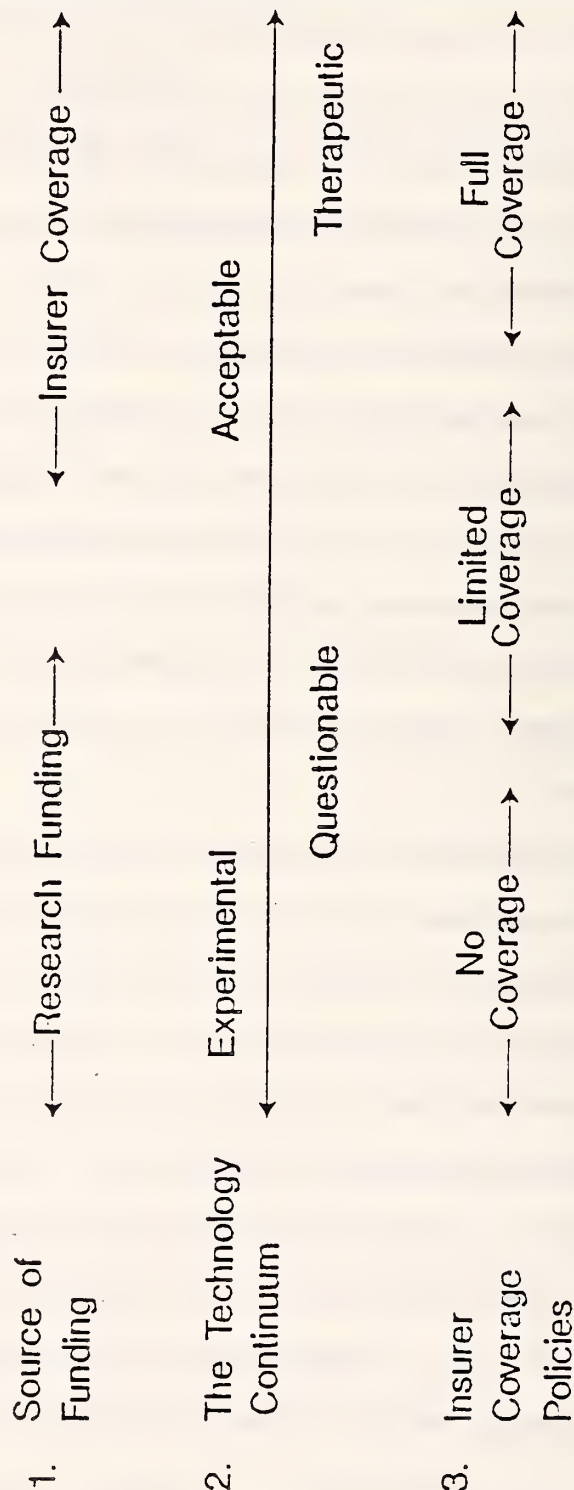
Since there is no single source of information to answer the foregoing questions, and because each insurer has what might be referred to as its own "technology assessment process," the insurance community, at times, seems inconsistent in its policies. Some insurers may cover certain procedures, and others may not. Some insurers may invoke limitations of coverage, others may not. Ultimately, it becomes evident that insurance policies are not adjudicated and applied uniformly! No small wonder that patients and providers are at a loss to explain why insurance seems to be an uncertain commodity. To be sure, as time passes, insurers may look to each others' policies in an effort to offer competitive benefits packages, but all this takes time. Moreover, for costly procedures, the coverage determination process can be very protracted, as no insurer looks forward to incurring sizeable losses if premiums are insufficient to cover claims.

It is interesting to note that private insurers have historically looked to Medicare for direction in the development of coverage policies (Hellinger,

1986:563). Hence, when Medicare extended coverage to liver transplants for persons 18 years of age and younger with rare congenital anomalies, so too did many private insurers. However, many private insurers developed coverage policies for heart transplants independent of Medicare, which did not announce its coverage policy until April, 1987. To this day, there are still private and public insurers who consider heart and liver transplants experimental and do not cover them for their beneficiaries. Of the private insurers, health maintenance organizations (HMOs) have become a major source of concern to transplant hospitals. HMOs are very restrictive in their coverage policies, often reflecting their preventive health care orientation. Other public insurers, such as the Medicaid program of Oregon, have reversed previously favorable coverage policies for some transplant procedures (Welch and Larson, 1988:171; 1988:1420). These decisions have been based on concerns related to resource allocation rather than the therapeutic status of the procedures.

Figure 16-1 graphically summarizes what can be referred to as the coverage and reimbursement continuum--a composite of three overlapping continua. They are: the source of funding continuum, the technology continuum, and the insurer coverage policies continuum. We begin our discussion with the technology continuum, along which all emerging, new and existing technologies can theoretically be placed. Along the technology continuum we have imposed several adjectives to describe the status of a procedure or technology--experimental, questionable, acceptable, and therapeutic. Related to the technology continuum are both the source of funding and insurer coverage policies continua as they relate to various

Figure 16-1: Conceptual Overview: The Coverage and Reimbursement Continuum



procedures. As shown, experimental and questionable procedures are the subject of research funding, while insurer coverage is applied to acceptable and therapeutic procedures. Finally, specific coverage policies vary but, in general, coverage is withheld for experimental procedures, whereas full coverage is made available for therapeutic procedures. For procedures that are questionable or acceptable, attention has begun to focus on limited coverage policies as a method by which insurers can ease the transition of technologies through the questionable and acceptable periods into the therapeutic stages. Through this approach, insurers are in some respects cost sharing in the development of procedures that would be more appropriately funded by various sources that fund clinical research (e.g., the National Institutes of Health). However, some sources of research funds, such as the NIH, have begun to restrict funding for some clinical research that it feels is an obligation of the insurance community. For example, "patient care" is not considered to be the responsibility of NIH and, therefore, investigators who choose to request patient care funds may find that such funds are subject to budgetary cutbacks. Clearly, we are in a period when the definition of what qualifies as research is changing. This is undoubtedly due to perceived funding restrictions, or the setting of research priorities that exceed the resources available to the granting agency.

Coverage of Organ Transplants

The foregoing discussion of the development of coverage policy and its relationship to innovation provides few insights as to the policies of public and private insurers today. Therefore, the following discussion will focus on the specific coverage policies of Medicare, Medicaid, and private insurers. In

addition, we will describe different reimbursement methodologies available to, or being used by, private insurers. We will begin with Medicare, given its dominate role in the development of coverage policy. We will then proceed with a discussion of Medicaid programs, and conclude, with an analysis of the policies of private insurers.

Medicare

Recall that the Medicare program, administered by the Health Care Financing Administration, has traditionally set the tone for both Medicaid and private insurer policies (Hellinger, 1986:563). Medicare has very vigorous and protracted procedures for determining what it will cover (Office of Technology Assessment, 1984). In addition to consulting with outside experts, commissioning special studies, and comprehensive internal review procedures, HCFA also seeks the input of other governmental agencies, such as the Office of Health Technology Assessment of the National Center for Health Services Research and Health Care Technology Assessment. Congress can also become involved through its research arm--the Office of Technology Assessment.

To qualify for Medicare, a person must meet at least one of the following conditions: (1) be age 65 or older, (2) be permanently disabled, or (3) have end-stage renal disease (Evans, 1986:425). Given current patient selection criteria, few people age 65 and over qualify for Medicare coverage for extrarenal transplants. The majority of patients who qualify for Medicare coverage of heart transplants do so because of disability, although as patient selection criteria are relaxed, people age 65 and over could conceivably qualify for heart transplants (Olivari *et al.*, 1988:258; Miller *et al.*, 1988:254; Land *et al.*, 1986:1).

Table 16-2 briefly summarizes the key features of Medicare coverage of kidney, heart, liver, and bone marrow transplants. As indicated, the most liberal conditions of coverage apply to kidney transplants. Only the usual medical restrictions of the Medicare program apply, and benefits are available on an entitlement basis. In the case of heart transplantation, there are both patient and provider restrictions and the benefits are not available as an entitlement. Liver transplant coverage is very restrictive and limited to children 18 years of age and younger. In fact, the criteria are so restrictive that Medicare has yet to cover a single liver transplant. Finally, bone marrow transplants are covered, provided the patient has leukemia or aplastic anemia. Other medical restrictions are also applied, and benefits are not offered as an entitlement. It is noteworthy that, at the present time, the Health Care Financing Administration is considering the possibility of extending Medicare coverage to adults with four indications for liver transplant.

At first glance, it may appear that Medicare is a major payer of organ transplants, however, this is true only for kidney transplants. Because of its very restrictive policies concerning extrarenal transplants, Medicare has been a minor insurer. Moreover, given concerns related to total program expenditures, it is doubtful whether Medicare will ever play a significant role in transplant coverage. This role would change only if indications for transplant are broadened, namely if the upper age limit for transplant is increased so that people age 65 and over would be considered acceptable candidates.

Table 16-2

Medicare Coverage of Transplants

<u>Transplant Procedure</u>	<u>(1) Restrictions/ (2) Coverage Scope</u>
Kidney transplant	(1) Usual medical restrictions (2) Entitlement program
Heart transplant	(1) Patient age approximately 50-55 years Minimal comorbidity Other medical restrictions (2) Not entitlement
Liver transplant	(1) Rare congenital anomalies Children 18 years of age and under (2) Not entitlement
Bone marrow transplant	(1) Leukemia or aplastic anemia (2) Not entitlement

Medicaid

As alluded to previously, Medicaid coverage of organ transplant procedures is both inconsistent and unpredictable (Intergovernmental Health Policy Project, 1985). The definition of persons eligible for coverage varies by state. In general, eligibles fall in three categories: (1) the categorically needy, (2) the medically needy, and (3) state only coverage (Gornick et al., 1985). As these categories suggest, Medicaid coverage is not easily obtained. In 1984, approximately 8.2 percent of the population was covered by Medicaid, about 5.9 percent having Medicaid coverage alone (Wilensky, 1988:133). Between 1980 and 1984, the proportion of the poor population with Medicaid coverage rose, even though the number of people on Medicaid stayed constant while the number in poverty increased.

Data on Medicaid coverage of organ transplants have been periodically collected by the Intergovernmental Health Policy Project at George Washington University (Intergovernmental Health Policy Project, 1985). Table 16-3 summarizes these data for 1985, 1986 and 1988. As indicated, coverage varies according to transplant procedure, underscoring differences among state Medicaid officials concerning the therapeutic status of each procedure. Kidney transplants and bone marrow transplants are covered by the majority of states, mirroring Medicare coverage policies.

In the future, it is possible that Medicaid policies will change as states attempt to deal with growing Medicaid expenditures and a limited resource base. Both Arizona and Oregon have attempted to constrain Medicaid expenditures by eliminating coverage for selected organ transplant procedures including heart, liver, and bone marrow transplants (Welch and Larson, 1988:171). This has resulted in residents of these states, seeking coverage in

Table 16-3
Medicaid Coverage of Transplants

<u>Transplant Procedure</u>	<u>Number of States Covering</u>		
	<u>1985</u>	<u>1986</u>	<u>1988</u>
Kidney Transplants	48 + DC	48 + DC	50 + DC
Heart Transplants	24 + DC	32 + DC	34 + DC
Liver Transplants	32 + DC	40 + DC	42 + DC
Heart-Lung Transplants	13 + DC	15	20
Pancreas Transplants	4 + DC	8	9
Bone Marrow Transplants	41 + DC	45 + DC	46 + DC

SOURCE: Intergovernmental Health Policy Project, George Washington University, Washington, D.C.

adjacent states where Medicaid coverage policies have been more liberal and residency requirements are minimal or nonexistent. For example, several residents of Oregon have sought transplants in the State of Washington at the expense of the residents of Washington State. This has led to Congressional hearings in Washington concerning the appropriateness of its coverage policies. Some state officials have even argued that Washington should follow the lead of Oregon by dropping coverage of some transplants in hopes that the resources saved could be used to provide other health care services intended to benefit a large number of people at relatively low cost. So far, health care policymakers have resisted and legislators have complied.

Private Insurers

Private insurers fall into four major categories: (1) the Blue Cross and Blue Shield plans, (2) the commercial insurers, (3) health maintenance and preferred provider organizations, and (4) self-insured plans. There is considerable similarity between the Blue Cross and Blue Shield Plans and commercial insurers. HMO's, PPO's, and self-insured plans are all hybrids with unique approaches to the delivery of health care services.

Few attempts have been made to canvass private insurers as to their policies concerning organ transplant coverage (National Task Force on Organ Transplantation, 1986; Hellinger, 1986:563; Health Insurance Association of America, 1983). This is, in large part, due to the regulation of the industry. During the deliberations of the National Task Force on Organ Transplantation, however, representatives of the private insurance community were most cooperative (Task Force on Organ Transplantation, 1985; National Task Force on Organ Transplantation, 1986), perhaps owing to the fact that both the Blue

Cross and Blue Shield national association, and the Health Insurance Association of America (HIAA), had representatives on the Task Force. Table 16-4 summarizes the results of survey data made available to the Task Force in 1985. Not surprisingly, liver and heart transplants were covered by many Blue Cross and Blue Shield plans, and by many plans represented by the HIAA.

Slightly more current data on private health insurers have been provided by Hellinger (1986:563). These data are summarized in Table 16-5. As indicated, information provided by the BCBS national association suggests that member plan coverage policies changed, and that now virtually all member plans provide coverage for heart and liver transplants.

Data from a survey of 65 commercial insurers conducted in conjunction with activities of the National Organ Transplantation Task Force are summarized in Table 16-6. As indicated in the table, coverage policies vary with some providing coverage as a standard practice and others on a case-by-case basis. In general, as Hellinger (1986:563) observes, these results show that commercial health insurers provide relatively broad coverage for organ transplants, and that they are more likely to reimburse for organ transplants than are HMO's. It is noteworthy that all commercial health insurers reimburse for services related to transplantation in the same way that they reimburse for other medical services.

In February, 1985, the Group Health Association of America, an HMO trade organization, surveyed its 120 members regarding their coverage of organ transplants at the request of the Task Force on Organ Transplantation. Only 67 members responded to questions about coverage of specific types of transplants. The results of the survey are summarized in Table 16-7. As is

Table 16-4
Private Insurer Coverage of Transplants

<u>Insurer</u>	<u>Percent Covering by Transplant</u>			
	<u>Heart</u>	<u>Liver</u>	<u>Heart-Lung</u>	<u>Pancreas</u>
Blue Cross and Blue Shield	80%	84%	72%	53%
Commercial Insurers (HIAA)	85	80	69	57
Group Health Association of American (HMOs)	30	74	23	18

SOURCE: National Task Force on Transplantation, 1986; Hellinger, 1986:563.

Table 16-5

Organ Transplant Coverage: Results from Recent Surveys

<u>Type of Transplant</u>	<u>Blue Cross/ Blue Shield (percent)</u>	<u>Commercial Insurers (percent)</u>	<u>HMOs (percent)</u>
Heart	100	85	32
Heart-Lung	72	69	15
Pancreas	52	57	13
Liver	100	80	81
Kidney	100	97	97
Cornea	100	100	100

SOURCE: Hellinger, 1986:563.

Table 16-6

Commercial Health Insurer Coverage of Organ Transplants (N = 65)

<u>Type of Transplant</u>	<u>Company Will Pay</u>			<u>Company Will Not Pay</u>
	<u>At request of policy-holder only</u>	<u>As a standard practice</u>	<u>On a case-by-case basis</u>	
Kidney	--	57	6	2
Heart	--	37	18	10
Heart-Lung	--	26	19	20
Pancreas	--	21	16	28
Cornea	--	54	11	--
Bone Marrow	1	51	14	--
Bone	--	45	15	5
Skin	--	49	14	2
Liver	--	33	19	13

SOURCE: Hellinger, 1986:563.

Table 16-7

HMO Coverage of Organ Transplants

<u>Type of Transplant</u>	<u>Basic</u>	<u>Rider</u>	<u>Other Case-by-Case</u>	<u>Total (67 Respondents)</u>
Kidney	52	1	12	65
Liver	35	1	18	54
Heart	8	1	13	22
Heart-Lung	6	1	10	17
Pancreas	3	1	9	13
Cornea	55	1	11	67
Bone Marrow	32	1	27	60

SOURCE: Hellinger, 1986: 563.

apparent from the table, in 1985 HMO's offered very limited coverage of extrarenal transplants, although coverage policies were favorable with respect to transplants covered by Medicare--kidney, cornea and bone marrow.

HMO's expressed concern over competition, given the possibility of adverse selection (Hellinger, 1986:563). For example, it was acknowledged that if a particular type of transplant was not covered by competitors, and it was covered by an HMO, those in need of the transplant would be likely to join the HMO. HMO's did not wish to acknowledge media vulnerability, arguing that clinical criteria were used to determine whether a specific transplant should be performed (Hellinger, 1986:563).

Virtually no data exists on the coverage policies of self-insured plans. Perhaps this is due to the fact that coverage policies are tailored to meet the needs of specific employers. At any rate, there is simply no way of gauging how liberal or conservative such plans may be.

Clearly, the foregoing are rather old data, given the rapidity with which change has taken place among insurers. Today, it is likely that a larger percentage of private insurers cover both heart and liver transplants, although it is unlikely that there has been much change in coverage policies pertaining to heart-lung and pancreas transplants. Moreover, it is likely that HMOs continue to be fairly conservative in their coverage of transplants.

Reimbursement Methodologies

As defined above, coverage is only one aspect of payment. The other aspect is reimbursement, and, in an increasingly competitive health care market, reimbursement may be more or less attractive based on the payment

methodology employed. Thus, it is important to point out several problems and pitfalls associated with reimbursement.

Today insurers have a variety of payment methodologies available to them. While most hospitals would prefer to recover the total charges associated with the care they provide, this has become unrealistic, as insurers pay more than hospital costs but less than patient charges. Payment methodologies in use today include: (1) payment of a percentage of actual charges, (2) payment on a per diem basis, (3) rate setting according to where the transplant is performed, (4) payment of usual customary and reasonable charges, (5) negotiation of a reimbursement rate, and (6) prospective payment (Intergovernmental Health Policy Project, 1985).

Depending upon the payment methodology followed, hospitals may make or lose money. Prospective payment rates may prove too low. Negotiated rates of payment may be adequate for the uncomplicated patient, but grossly inadequate for the complicated patient. In many instances, in a direct sense hospitals lose money on transplants, although they may indirectly benefit from the visibility that transplant programs create. As a result of this visibility, patients with other health problems may seek care at a hospital believed to offer the latest technological innovations, transplantation being among these. More importantly, however, given the focus of this chapter, it is possible that patient discrimination could occur not only based on ability to pay, but based on the payment methodology that the patient's insurer plans to follow. In this regard, both Medicare and Medicaid patients would be less attractive than patients covered by private insurance. If such discrimination were to occur, questions are likely to be raised concerning patient access to transplantation, and the quality of care offered to those patients who have

public health insurance. Once again, this is a generic issue that applies to all of health care, not just organ transplants.

Conditions of Access

Having now established that ability to pay is a very real concern of at least one in four Americans, it is worthwhile considering how the general public views the selection of transplant recipients, given concerns related to ability to pay. Elsewhere Caplan has noted that "... Americans feel very strongly that life-saving treatments ought to be provided to all whom might benefit from them, regardless of the individual recipient's ability to pay. Community pride and support for heart transplant centers is not based on the provision of lifesaving operations for the wealthy and insured but on the provision of care to desperately ill patients regardless of ability to pay." (Caplan, 1987:10) Caplan further observes that "... members of the public feel that the use of a 'green screen' requiring that those in need have the ability to pay for surgery should not be used to ration hearts and other scarce solid organs." Although true, these observations seem violated when it is recognized that, in a 1985 a survey of the American Society of Transplant Surgeons, 78 percent of the respondents indicated that a patient's ability to pay for their treatment influenced the surgeon's selection of transplant candidates (Goeken, 1985). Moreover, 38 percent of the surgeons said that ability to pay for immunosuppressive medications influenced their selection of transplant candidates (Goeken, 1985).

In January, 1987 the Battelle Human Affairs Research Centers was contracted by the United Network for Organ Sharing to conduct a national survey of "Public Opinion Concerning Organ Donation, Procurement, and

Distribution" (Evans and Manninen, 1988:781; Evans, 1987:13). In an introduction to the survey, people were made aware of the fact that there were simply not enough organs to meet the need for transplantation. It is interesting to note that over 88.0 percent of the population agreed with the following statement:

Regardless of how patients are selected for transplant operations, I am most concerned that donor organs are distributed as fairly and equally as possible.

Moreover, over 80.0 percent of the people surveyed agreed with the following statement:

Medical need, not social or economic factors, should be the only criterion used to select transplant recipients.

Clearly, the public is very concerned about the process used to distribute donor organs, as well as the criteria used to select transplant recipients.

To more precisely assess public opinion concerning the use of a whole range of social criteria, we asked the following question in our survey:

Recognizing there are not enough organs to go around, and difficult choices must be made in deciding who will get them, how strongly do you agree or disagree with each of the following statements?

The exact statements and the responses are summarized in Table 16-8. The most significant criteria in order of importance are the following (Evans and Manninen, 1987):

<u>CRITERION</u>	<u>PERCENT AGREEING</u>
Patient will survive and benefit	83.3%
Patient able to return to work and regular activities	71.9%
Sickest patients should have preference	71.1%
Younger patients over older patients	56.8%
United States citizens over all other patients	51.7%

Table 16-8

Public Opinion Concerning the Use of Specific Medical and Social Criteria in the Selection of Transplant Recipients

	<u>Strongly Agree</u>	<u>Agree</u>	<u>Disagree</u>	<u>Strongly Disagree</u>	<u>No Opinion</u>
Preference should be given to younger rather than older people	10.6	46.2	28.7	2.9	11.6
Preference should be given to the sickest patients	11.6	59.5	18.4	0.9	9.7
Preference should be given to U.S. citizens over <u>all</u> other patients	9.3	42.4	35.5	3.7	9.1
Preference should be given to those who can afford them	0.5	7.7	61.4	25.6	4.9
Preference should be given to people with a strong religious background	0.2	5.2	68.3	21.4	4.9
Preference should be given to people who do <u>not</u> drink alcohol	1.6	17.8	62.5	11.1	7.1
Preference should be given to people who are most likely to survive and benefit	17.3	66.0	10.9	0.5	5.4
Preference should be given to those who are most likely to be able to return to their usual work and/or household activities	10.2	61.7	19.6	1.2	7.3
Preference should be given to people who do <u>not</u> smoke	2.7	23.6	56.9	7.8	9.0
Preference should be given to people who live a "healthy" lifestyle	2.8	37.9	44.8	4.5	10.0

SOURCE: Evans, 1987:13; Evans and Manninen, 1987.

People who live a "healthy" lifestyle	40.7%
People who do <u>not</u> smoke	26.3%
People who do <u>not</u> drink alcohol	19.4%
People who can afford them	8.2%
People with a religious background	5.4%

These results indicate that the public does not necessarily discredit people in the patient selection process if they engage in unhealthy behavior (e.g. smoking, drinking). Also, it is obvious that people strongly object to the use of an economic criterion. Ability to pay is not viewed favorably. While surviving and benefitting may be considered a clinical indicator of success, ability to return to work or usual household activities is most certainly a social criterion--one frequently used in the pre-Medicare dialysis era for selecting dialysis patients (Evans *et al.*, 1981:487). Thus, people appear to be somewhat inconsistent in their choice of selection criteria. They seem to acknowledge some role for social criteria, but no role for economic criteria in the selection of transplant recipients.

As already discussed above, the National Task Force on Organ Transplantation was also very concerned about the use of economic criteria in the selection of transplant recipients (National Task Force on Organ Transplantation, 1986; Brock, 1988:86). The Task Force concluded that "... the federal government should ensure that all patients have access to all efficacious organ transplantation procedures, regardless of ability to pay." Two arguments were cited in support of this position. These were the following: (1) the commitment of society to meet basic health needs, and (2) the special nature of organ transplantation, given that organs are a public resource.

With regards to the first argument, the basic point was simple. Heart and liver transplantation were both found to be equally if not more cost-effective than other lifesaving procedures currently covered by public and private insurers. Our society is already committed to funding a variety of basic health care needs. Given this commitment, the Task Force determined it was "... arbitrary to exclude one life-saving procedure while funding others of equal life-saving potential and cost."

With respect to the second argument, the Task Force concluded that "Whether or not there is an obligation to provide equal access to health care, it seems unfair and even exploitative for society to ask people to donate organs if those organs will then be distributed on the basis of ability to pay." In short, organs are a public resource and all members of the public who need a transplant should have equal access to an organ.

As noted previously, the Task Force felt that it was essential that a public program be set up to cover the costs of transplants for medically eligible recipients who were uninsured, underinsured, or simply lacked the resources to cover the cost of their transplant. At the time the Task Force completed its work, it was estimated that the cost of a public program required to meet the needs of patients without insurance for transplantation would be between \$13.2 and \$35.4 million annually (National Task Force on Organ Transplantation, 1986). These figures, of course, are subject to change based upon the indications for transplant, and the availability of donor organs. Clearly, given the current constraints on donor organ availability, it is doubtful that the higher estimates would be realized (Evans et al., 1986:1892). Therefore, even today, with the supply of donors remaining relatively constant, it is unlikely that the costs associated with a public

program, such as that proposed by the Task Force, would not be excessively high. However, it could be argued that any additional expenditures for transplantation are excessive, given other health care needs.

Clearly, the Task Force addressed the issue of the uninsured transplant candidate head-on. As of this time, no realistic solution has been offered to resolve the economic problems that transplant candidates may increasingly face, although legislation has been proposed to start a national fund for needy patients (Senate Bill S2409). Unfortunately, the limited experience with funds, such as that of Massachusetts, has not been impressive. In fact, it might be argued that such legislation could be counterproductive, since the need to develop other more creative approaches to the problems of the uninsured transplant candidate may not be forthcoming. In other words, a transplant fund might do little more than create the impression that something is being done at the federal level to deal with the uninsured patient. For this reason, the Board of Directors of the United Network for Organ Sharing failed to pass a resolution in support of the proposed legislation.

Discussion

To what conclusion does the foregoing lead? Should ability to pay ever be a consideration in gaining access to transplantation? In the final analysis, one must be realistic and distinguish among three separate questions regarding ability to pay as an access barrier to transplantation. These questions are as follows: (1) Should ability to pay ever be a consideration in gaining access to transplantation? (2) Will ability to pay ever be a consideration in gaining access to transplantation? and (3) Is ability to pay

ever a consideration in gaining access to transplantation? The answer to the first question is an emphatic "no!" Since the answer to the third question is "yes," the answer to question two is a foregone conclusion as well--"yes."

Ability to pay should not be an obstacle to transplant. The entire practice of rejecting patients for transplant based on their ability to pay is distasteful, as well as morally and ethically wrong. In a nation such as ours, people deserve better. However, although accounting is inadequate, we know that some people are being denied access to transplantation because of their inability to pay. In this regard, our health care delivery system operates in an insidious manner, similar to the British system so well described by Aaron and Schwartz.

In their book, The Painful Prescription, Aaron and Schwartz describe the delivery of dialysis in the United Kingdom (Aaron and Schwartz, 1984). They note that patients are simply not referred by general practitioners (GP) to nephrologists for dialysis, if the patients are not considered to be suitable candidates (e.g. they may be too old). Thus, when a nephrologist is asked if they deny patients dialysis, their response is "no." However, the screening has already occurred at the level of the G.P., without the knowledge of the nephrologist. By analogy, it is likely that some United States patients who could benefit from a heart or liver transplant are not referred to a transplant center by a cardiologist or hepatologist, because of financial and insurance considerations, even if the patient could have benefitted from a transplant. Other patients without the appropriate financial means who are referred are forced to engage in public fund raising efforts. While the failure to refer a patient for transplant is deplorable, and efforts to raise public funds an

unacceptable solution, perhaps, oddly, the failure to refer is a more humane and publicly tasteful course of action.

Unfortunately, it is possible that more patients will be denied access to transplantation, based on ability to pay. Gradually, legal concerns related to the failure to refer may lead physicians to make prompt referrals, even though a patient may lack the economic resources for transplantation. We know that more and more patients are being referred for transplant, as the waiting lists have grown. This will further increase the burden on transplant centers to make appropriate patient selections. However, as our data have shown, people do not readily accept discrimination based upon economic factors.

Unfortunately, there is no clearcut solution, because the problem we face is generic to the delivery of health care services in the United States. While one can argue that patients should have access to transplantation, regardless of their ability to pay, their inability to pay creates special demands on the health care system that many other patients are unable to make (Scitovsky and Rice, 1987:5; Andrulis et al., 1987:1343; Arno, 1987:1376; Bloom and Carliner, 1988:604; Scitovsky, 1988:32). Is it fair to create a payment source for transplants that is not available to patients with other health care needs?

It should also be recognized that patients who are well-insured, and have considerable wealth, have access to health services and providers to which other economically-disadvantaged patients do not have access. For example, the local county hospital may not provide the same quality of health services as the private hospital frequented by the wealthy. Wealthy patients are free to pick and choose as they see fit, and it is ridiculous to assume

that constraints can be imposed on their choice of providers simply to assure that people have equal access to equal care.

Moreover, there are parallels between access to transplantation and access to experimental and innovative therapy (Antman et al., 1988:46; Goldworth, 1987:8). For example, cancer clinics are now operational that cater to the needs of patients who have apparently exhausted all therapeutic options and are willing to pay to receive experimental therapy. Clearly, the indigent patient is not able to gain access to such services because they lack the financial resources. Is this unfair in the same way that denial of a transplant on economic grounds is unfair? Is the argument that donor organs are a public resource sufficiently persuasive to give everyone an equal claim to them?

Finally, it is possible that innovation in health care will be threatened by restrictive coverage policies. Gradually, the focus of attention may not be on the coverage of procedures that are marginally therapeutic, but on procedures that are effective yet costly. In effect, we are working the margins of what is an acceptable price to pay for effective medical care. For example, if a totally viable mass-produced artificial heart became available tomorrow, are we capable of generating the resources required to provide it to those patients in need (Lenfant, 1986:27; Swazey et al., 1986:387; Booth, 1988:976; Culliton, 1988:283)? If we are not, then we may be beginning to realize that life has a price, but one that is not worth paying, given limited resources. If this should be the case, perhaps we should better target our research and development efforts by proceeding with medical research (not medical care) that can be predicted, a priori, to be cost-effective. In other words, we should target for development those technologies that have the

potential to save the most lives at the least cost. Following this approach, we would radically alter the scientific enterprise in the United States as we now know it. Grant research would be replaced by contract research and basic research would take a back seat to applied research. Moreover, university researchers would play a secondary role as private research institutes and industry would take the lead in both research and development.

Ultimately, it is difficult to justify economic discrimination in access to transplantation (Monaco, 1987:1). Yet, at the same time, one must be sympathetic to the concerns of both public and private insurers, as well as those, who argue that at some point we must draw a line with regards to the level of medical care that we can provide, given competing health and social needs (Evans, 1983:2047; 1983:2208; Angell, 1985:1203; Crawshaw et al., 1985:3213; Cohen, 1986; Churchill, 1987; Daniels, 1986:1380; 1986:1297). If the public insists that everyone should have equal access to transplantation, then it must also recognize that this cannot be accomplished without increasing health care expenditures. And to meet these rising expenditures, the public must be willing to live with increased taxes to fund public insurance programs and/or higher insurance premiums to fund private insurance benefits. Since most private insurance is provided as an employer benefit, employees may be faced with higher deductibles and copayments. Alternatively, employees may negotiate for better health benefits and lower wage increases. In the end, it is apparent that we all pay one way or another, and that insurers essentially serve as prudent stewards of the resources they command on behalf of the individuals they represent.

Ultimately, we must ask ourselves what are we willing to pay in order to avoid making decisions about medical treatment based on an ability to pay

criterion. The ESRD Program came into existence as a mechanism by which to avoid the problems attendant to the selection of dialysis patients (Evans et al., 1981:487). By making more funds available, the same approach could be used to resolve the transplant dilemma. It appears, however, that our actions are beginning to speak louder than our words--we seem willing to deny people access to treatment, given recent health care policy decisions, even though we claim that economics should not be a consideration in determining who gains access to transplantation.

CHAPTER 17

THE DESIGNATION OF CENTERS FOR SPECIALIZED HEALTH CARE SERVICES

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Introduction

Recently there has been much discussion regarding the merits of the general concept of "centers of excellence" or "designated centers" for purposes of providing various specialized medical and surgical services (Ross, 1987:219; Zuck, 1987:397; Walshe, 1987:397; Robinson *et al.*, 1987:85; Roos and Lyttle, 1987:130). Those who favor designation argue that costs are contained and quality is assured by limiting the unnecessary duplication of facilities (McGregor and Pelletier, 1987:179; Finkler, 1979:266; Luft *et al.*, 1986:83). Others disagree, noting that designation discourages competition and, therefore, costs are likely to be higher (Robinson *et al.*, 1987:85). Moreover, opponents of designation argue there is little evidence, citing the Medicare prospective payment system, that quality is jeopardized by competition (Eggers, 1987; McCarthy, 1988:1683). It is interesting that the concept of limiting services to selected providers has emerged with vigor at a time when competition has gained its strongest foothold in the provision of health care services (Fuchs, 1988:5; Enthoven, 1988:25).

Not surprisingly, whether or not it is appropriate to designate centers for specialized health care services often degenerates into a near ideological debate between the forces that favor competition, and those convinced of the value of regulation. It is my thesis that such debate is largely counterproductive since, in actuality, both sides appear to agree on the merits of designation, once the concept is properly understood, and the goals it is intended to achieve are clearly delineated. Therefore, the basic objective of this paper is to outline the areas of agreement and disagreement between the procompetition and the proregulation perspectives on the delivery of health care services.

Background

The origins of the general concept of designated providers can, at least, be traced to the era of Regional Medical Programs, where a primary consideration was the regionalization of services throughout the United States with the goal of improving patient access. However, developments related to the concept of designation have been more profound in the past decade as both public and private insurers find the concept to be attractive. In the past several years, Medicare, some Medicaid programs, numerous Blue Cross and Blue Shield plans, as well as many commercial insurers, have all implemented designated provider policies for a variety of specialized services, as the brief review which follows so indicates.

In November, 1979, the Health Care Financing Administration (HCFA), following the advice of the National Heart, Lung and Blood Institute, tentatively authorized payment for heart transplants, but only if they were performed at Stanford University Medical Center (Newman, 1980:52296). This was the first time that Medicare limited reimbursement for a medical procedure to a single institution (Hellinger, 1982:307; Reiss *et al.*, 1982:399). On August 6, 1980, amidst controversy as to the appropriateness of this decision, HCFA gave notice that heart transplantation would be excluded from Medicare coverage, effective June 13, 1980 (Newman, 1980:52296). This decision was based on continuing uncertainty with regard to patient selection, potential social and economic implications, and a lack of sufficient information to support the development of generally applicable coverage criteria. A national study, hereafter referred to as the National Heart Transplantation Study, was to be conducted to address these issues (Knox, 1980:570; Newman, 1981:7072).

In March, 1982, the Medical Policy Committee (MPC) of Blue Shield of California made a coverage decision as equally profound as that of Medicare, but with landmark implications for the private health insurance industry. The MPC announced that reimbursement for percutaneous transluminal coronary angioplasty would be limited to physicians and institutions that met standards for its performance, as defined in a report of an ad hoc subcommittee of the executive committee of the National Heart, Lung and Blood Institute's Percutaneous Transluminal Coronary Angioplasty Registry (Bunker et al., 1982:620). This was followed by two further decisions by the MPC allowing for "selective coverage" of emerging technologies that were generally considered investigational but, in the hands of experienced clinicians, would be deemed acceptable and, therefore, covered (Schaffarzick, 1987:84). These decisions concerned both heart and liver transplantation. In 1984 the MPC determined that heart transplantation would be covered when performed at Stanford University, or "...any other institution that could document skill, resources, commitment, and favorable outcomes comparable to those of Stanford." (Schaffarzick, 1987:84). The same concept of selective coverage was extended to liver transplantation based on a National Institutes of Health Consensus Development Panel Report (Consensus Conference Report, 1983:2961).

The concept of selective coverage was pioneered by Schaffarzick and his colleagues as an approach to promote "...the improvement of clinical outcomes and the desirable goal of regionalization." (Bunker et al., 1982:620; Schaffarzick, 1987:84). The rationale for this innovative strategy stems from a concern that institutions and physicians who wish to be reimbursed for providing specialized services must be prepared to make a sustained

commitment of time, skilled personnel, space and money. It is assumed that such an investment will "...discourage the undue proliferation of facilities and enhance the numbers of patients being treated in established institutions", while at the same time promoting quality care.

More recently, the final decision by the Health Care Financing Administration (HCFA) to limit Medicare reimbursement of heart transplants to hospitals meeting various facility and staff requirements, as well as outcome standards, is significant (Roper, 1987:10935; Renlund et al., 1987:873). Similarly, some commercial insurers, most recently Prudential Insurance Company of America, have announced programs that require policyholders to undergo heart, kidney, or liver transplants at select hospitals considered to have acceptable survival rates (Health insurer is selecting hospitals for transplants, 1988). This approach has been previously endorsed by the Health Insurance Association of America (HIAA), has been recommended by the Benefits Management Division of the National Office of the Blue Cross and Blue Shield Association, and was supported by the National Task Force on Organ Transplantation (Health Insurance Association of America, 1985; Technology Evaluation and Coverage, 1985; National Task Force on Organ Transplantation, 1986). It is also of interest to note that the Civilian Health and Medical Program of the Uniformed Services (CHAMPUS) program has developed very specific guidelines for reimbursement of liver transplant procedures (Lawson, 1985:26222). In announcing its program, Prudential officials indicated that they hoped to "stem spiraling medical costs" and offered "volume in exchange for cost discounts." The decision by Prudential is very significant since other commercial insurers may adopt similar policies, and the designated centers approach may be extended to other procedures. In

the spirit of competition, Prudential was able to negotiate discounts of 25 to 30 percent with selected institutions for transplant procedures. To induce beneficiaries to use designated hospitals, Prudential includes coverage of travel costs for the patient and a companion. The HIAA supported Prudential's policy by citing two distinct advantages, previously recognized and acted upon by Blue Shield of California. First, an industry representative noted that when only a few hospitals perform a high volume of transplant procedures, outcomes are likely to improve. Second, designated hospitals are expected to prevent unnecessary duplication of facilities, ultimately containing costs. Prudential plans to expand the system to include other complex and costly procedures, including bone marrow transplants, coronary artery bypass surgery, burn treatment, and numerous nonsurgical procedures.

Centers of Excellence, Designation, and Regionalization

Unfortunately, there is a tendency to use the concepts of "centers of excellence" and "designation of centers" interchangeably. This is an error. The concept of centers of excellence is volatile, and detracts from the basic issue at hand. Therefore, the concept of designation is preferable when discussing limiting or restricting the provision of health services, whether or not targeted reimbursement is involved. (Similarly, the use of the term proliferation of centers is inflammatory and should be avoided.) In short, simply because a center is a designated provider does not mean that it is a center of excellence, nor is a center of excellence necessarily a designated provider of services. Excellence is a relative concept. On the contrary, designation is categorical--a provider is designated, or is not.

In discussing designation, it is difficult to avoid the concept of

regionalization. However, the regionalization of health care services is a sufficient, not a necessary condition for designation. Unlike the concept of designation, regionalization implies geographical distribution. For example, trauma centers and neonatal intensive care units are often regionalized based upon geographic considerations (McCormick et al., 1985:799; Pritchard, 1985:1220; Miller and Jones, 1985:1141; Rosenblatt et al., 1985:429; Rudolf and Borker, 1987; West et al., 1988:3597). Alternatively, it is apparent that other specialized services, such as open-heart surgery facilities, or organ transplant centers, may be concentrated in relatively small areas. In this regard, several years ago Moore recommended that heart transplant programs be regionalized, suggesting that they "... should coincide approximately with census districts or Army Corps areas." (Moore, 1982:254). More recently, Russell has considered the merits of the consortium approach to the provision of transplantation services (Russell, 1986:867).

A conflict arises when the goals of designation are confused with those of regionalization (Russell, 1986:867; Longmire and Mellinkoff, 1979:1393; Bunker et al., 1982:657; Peterson and Bloom, 1983:179; Luft, 1985:125; Donabedian, 1984:95). The primary goal of regionalization, as implied here, is to assure the geographic distribution of specialized services, while limiting their diffusion. As already noted, the Regional Medical Programs of several years ago were intended to make medical services available throughout the United States (Starr, 1982). Access, not quality, was the major consideration. Although quality is a secondary goal of regionalization, it, along with cost containment, is a primary goal of designation (Finkler, 1981:325).

It is important to recognize, however, that even under designation, quality is a relative concept. Designated providers may differ in the overall

quality of care they provide--some providers will have better outcomes than others, subject to patient case-mix considerations. However, by imposing restrictions on providers, the intent is to limit the range of variability in the quality of services provided. It is noteworthy in this regard that the United Network for Organ Sharing (UNOS)--the national network for the procurement and distribution of donor organs--in establishing its criteria for transplant program membership, chose not to embrace a specific survival rate programs must attain, but rather to periodically review those transplant programs whose survival rates are found to be among the lowest five percent in the nation (United Network for Organ Sharing, 1988). Alternatively, the Health Care Financing Administration (HCFA), in its designation of heart transplant programs, stated that centers must have an overall one-year patient survival rate of 73 percent, and an overall two-year patient survival rate of 68 percent to qualify for reimbursement (Roper, 1987:10935). Although UNOS and HCFA differ in their approach to designation, the intent is the same--to establish a threshold level of patient survival that transplant programs must attain. Yet, it is clear that many programs have survival rates that exceed the threshold levels.

The designation of centers approach to the provision of specialized services has not been enthusiastically embraced by the medical and hospital communities. On grounds of restraint of trade, both the American Hospital Association, and the American Medical Association, have objected to the designation of providers (Merriken and Overcast, 1985:481). Upon close examination of the criticism, as already noted, it is apparent that two separate viewpoints prevail, one favoring competition and one that supports regulation. It is my hypothesis that the pro-competition and pro-regulation

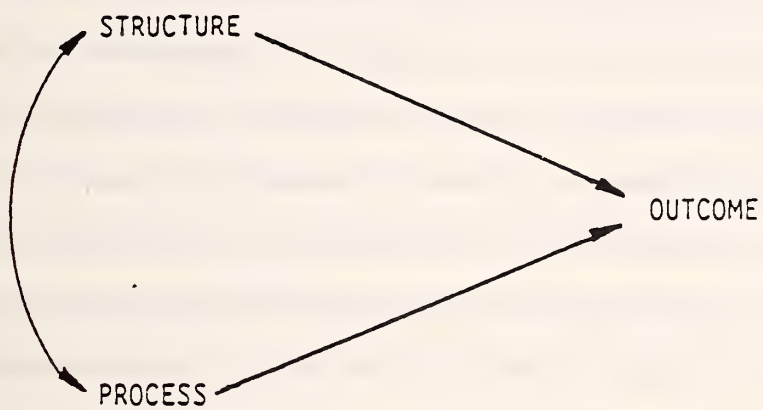
forces differ, not necessarily with regard to the value of designation, if supported by empirical research, but rather with respect to the concept of regionalization. In principle, regulators probably have few objections to linking the concept of designation with that of regionalization, while the pro-competition forces would, in nearly all instances, reject the concept of regionalization. In short, regionalization is a concept incompatible with competition.

Quality Assurance

Commentators who favor competition, as well as those who are partial to regulation, express interest in providing quality services. In general, however, a shift has occurred in what are considered to be the most appropriate indicators of quality (Donabedian, 1980; 1982; 1985; Bowen, 1987:1578). Within the competition perspective, structure and process measures have been de-emphasized, and outcomes have been accorded priority. Although arguable, it has been assumed, historically, that favorable outcomes naturally follow from adequate structure and process (Starfield, 1974:39; Brook *et al.*, 1976; Wenneberg *et al.*, 1980:277; Brook and Lohr, 1987:3138; Schroeder, 1987:160; 1987:251; Scher, 1987:171; Ellwood, 1988:1549; Laupacis *et al.*, 1988:1728; Caper, 1988:1535; Lohr, 1988:37; Donabedian, 1988:173). The regulatory perspective continues to subscribe to this view.

Conceptually, discussions of quality of care have tended to suggest that one must choose among various indicators, either structure, process, or outcome measures, in making a quality of care assessment. However, as shown in Figure 17-1, structure and process measures are perhaps best viewed as correlated with each other, each serving as determinants of outcomes.

Figure 17-1
Relationships Among Quality of Care Indicators



In short, outcomes are causally related to medical care structure and process, while the latter two indicators are correlated with each other. A synthesis of the regulatory literature suggests that to achieve acceptable quality of care outcomes, an adequate structure and process must be assured.

Not surprisingly, those commentators who favor competition, and those partial to regulation, differ with respect to how quality of care can be best assured. For example, those who favor competition tend to focus on outcomes as the most acceptable indicator of quality. It is argued that if all providers have approximately equivalent patient outcomes, there is little need to focus on other indicators of quality. The regulatory perspective is more conservative and subscribes to the view that quality is best assured if structure and process criteria are invoked, along with performance standards. The rationale is relatively straightforward. Outcomes are assumed to follow from structure and process. Therefore, if one wants to assure quality, one must focus attention on structure and process. Regulators are concerned that if structure and process measures are ignored, even on a temporary basis, patient outcomes could well be jeopardized as providers attempt to establish a "track record" that will later serve as the basis for bona fide designation evidenced by performance. For example, if no attempt is made to encourage heart transplant programs to comply with a minimal level of medical care structure and process, because outcomes are ultimately the primary focus of attention, it is conceivable that many patients may experience adverse outcomes as a result of poor structure and process. Consequently, lives will be lost, and donor organs wasted.

While the interest in outcomes is considered by most to be a positive development, it is evident that neither structure nor process indicators can be

completely ignored. If it is assumed that there is at least a minimal relationship between structure, process, and outcome, and that outcomes have a lagged temporal association with medical care structure and process, it then follows that, when in doubt, efforts should be made to assure a basic level of structure and process. This is accomplished under the regulatory perspective, for example, by making compliance with various facility requirements and staffing patterns necessary (Schaffarzick, 1987:84). Flexibility is critical, however. If it is later demonstrated that such requirements bear no empirical association with patient outcomes, their use should be suspended as invalid. Ultimately, neither the regulatory nor the competitive perspective questions the relevance of an outcome approach to quality. In the final analysis, however, a multiple indicator approach to quality of care assessment appears prudent unless, or until, one or more sets of indicators have been found to lack an empirical basis.

Patient Advocacy

The debate as to what criteria one should use to designate providers of services is volatile, and, not surprisingly, the role of the patient is in dispute as well. Pro-competition forces assume an active, knowledgeable, patient capable of discriminating among the providers of a service. If the outcomes of a particular provider are poor, it is expected that patients will choose to go elsewhere for their care. Given this, to remain competitive, it is assumed that hospitals with poor outcomes will make the required changes to improve the quality of service they provide.

Regulators are uncomfortable with this laissez faire approach, and point out that available evidence suggests that patients do not change providers

based upon their knowledge of outcome data (Valdeck et al., 1988:122). Therefore, to protect the interests of the patient, they act on behalf of the patient by supporting the use of both structure and process criteria in an effort to assure quality outcomes. Thus, in the provision of transplantation services, they might offer recommendations as to what constitute appropriate laboratory facilities (i.e., structure) and minimum patient management protocols (i.e., process) (Schaffarzick, 1987:84). If these are adequate, it is believed that patients receiving care at centers meeting these criteria will have outcomes of acceptable quality. In short, patient outcomes are not expected to be jeopardized, even on a short-term basis. In summary, under competition, the patient is his or her own advocate while, under regulation, those responsible for establishing the conditions that govern providers serve as the patient's advocate.

Because of differing perspectives as to the role of the patient in choosing a provider of services, proregulation and procompetition forces also differ with respect to the public release of provider-specific outcome data (Wagner et al., 1986:148; Luft and Hunt, 1986:2780; Moses, 1986:2801; Anonymous, 1986:1376; Dubois et al., 1987:1162; 1987:1674; 1988:1624). The decision by the Health Care Financing Administration to release hospital-specific mortality data is an excellent case in point. Pro-competition forces believe this is a positive step, since patients can determine which providers have the best outcomes, and can choose where they want to be treated. Under this scenario, an informed consumer is a smart consumer. Pro-regulation forces are more skeptical and tentative. They believe that the patient is not capable of fully appreciating the complexity of publicly released data. For example, they may insist that the data be carefully controlled for

patient case-mix, as well as regional variations. While some patients may be capable of interpreting such data, the majority are assumed to be clinically naive. Regardless of the validity of the data, the mere fact of its release has received the attention of the hospital industry and many hospitals are taking quality of care, particularly in relation to outcomes, much more seriously.

While there are advantages to the public release of institution-specific patient outcome data, there are other problems in addition to the crudeness with which they are often made available. First, the majority of patients may pursue treatment at only the very best institutions, thus, resulting in an imbalance in the patient referral network. Second, although it is already the case, wealthy patients have a greater propensity to receive care at the best institutions. They have the resources to travel. Finally, institutions may engage in cream skimming to achieve or maintain a superior track record. Thus, patients with an adverse clinical profile may find it difficult to locate a treatment center that will accept them. These problems are by no means simple, and each becomes increasingly complex in a health care delivery system geared to outcome criteria.

Patient Access and Designation Policies

Patient access is not necessarily adversely affected by designating centers for specialized services, as is often argued by persons who favor competition. Patients may still have a choice of providers in a confined area, despite designation. Alternatively, regionalization almost always implies that access is potentially limited because of imposed geographical constraints. Of course, the extent to which access is limited depends upon what geographical

criteria are used to accomplish regionalization. In this regard, a population ratio criterion (e.g., one kidney transplant center per million population) may limit access to a far greater extent than, say, a distance to regional facility criterion (e.g., one kidney transplant center per 200 mile radius). It is noteworthy that in developing its program of designated providers for transplant services, the Prudential Insurance Company of America was concerned with regionalization, as well as designation. Therefore, although few in number, Prudential's designated centers are geographically disparate, thus enhancing patient access.

Unfortunately, patient access arguments are often used to undermine the intent of designation policies. This is a mistake, provided designation policies are based on empirically demonstrated quality of care criteria. Access to a facility providing an acceptable level of quality should be the foremost consideration. Access for the sake of access is hardly in the patient's best interest.

Elective Designation

There are instances where designation of providers may be indicated using an arbitrary volume criterion (e.g., number of procedures performed annually) as a method to limit the diffusion of medical and surgical procedures (Bunker *et al.*, 1982:620; Schaffarzick, 1987:84). This policy is hereafter referred to as "elective designation." This is justifiable when the following conditions exist: (1) an investigational or experimental procedure is being applied and (2) the relationships among structure, process, and outcome quality indicators have yet to be empirically established for a procedure that is rapidly diffusing. A volume criteria in each of these instances is intended

to accomplish the following: (1) to allow investigational procedures to achieve therapeutic status in a controlled and orderly manner and (2) to limit the diffusion of procedures that are considered therapeutic only in the hands of a relatively small number of individuals at very few institutions (Schaffarzick, 1987:84). By analogy, it is noteworthy that elective designation essentially occurs in clinical trials of the vast majority of new drugs, and in the application of some medical and surgical procedures.

There are at least two methods by which elective designation can be implemented. First, clinical sites may be chosen based upon their willingness to participate in a clinical trial of a new procedure or a drug. Second, specific criteria may be developed with which clinical sites already providing a service must comply. It is in this latter instance that a volume criterion may have utility. For example, participation in a program that links reimbursement with experience illustrates this approach. HCFA has taken this approach in its designation of heart transplant centers eligible for Medicare reimbursement. There are at least two reasons for this. First, under HCFA guidelines, the objective is to force hospitals to establish a track record independent of Medicare reimbursement in order to qualify for participation in the Medicare program. Hospitals are expected to expend their own research and development resources, or those obtained from private or public sources, to establish a track record acceptable to HCFA. Alternatively, if hospitals can convince other public and private insurers to pay for transplants they perform, these insurers, by analogy, essentially provide the research and development resources that "unqualified" hospitals require to establish a track record acceptable for Medicare program participation.

A second reason HCFA developed a policy of designation owes to the absence of empirical evidence refuting the relationship among structure, process, and outcome quality of care indicators. Thus, HCFA adopted a clinically conservative approach by establishing both structure and process criteria for Medicare program participants, as well as outcome performance standards. Should it eventually be determined that structure and process measures have no relationship to outcomes, it is likely that HCFA will suspend the use of structure and process indicators in its designation of transplant centers.

It is important to point out that elective designation does not necessarily imply regionalization. HCFA chose not to regionalize heart transplant centers, it simply set what were believed to be prudent conditions for participation in the Medicare program, given concerns about the cost and quality of patient care. Whenever elective designation policies are invoked, a similar rationale should be applied.

Finally, as already noted, private insurers have also been supportive of elective designation of providers (Bunker et al., 1982:620; Schaffarzick, 1987:84; Health insurer is selecting hospitals for transplants, 1988; Health Insurance Association of America, 1985; Technology Evaluation and Coverage, 1985). There are several reasons for this. They include the following: (1) quality of care, (2) cost of care, and (3) uncertainty surrounding what are viewed as investigational procedures. Private insurers have not been reluctant to use minimum volume requirements, assuming a positive correlation between the volume of procedures performed and patient outcome, and a negative correlation between the volume of procedures and the cost of care (Luft et al., 1979:1364; Luft, 1980:940; Farber et al., 1981:200; Roberts and Cretin,

1981:666; Flood et al., 1984:98; 1984:115; Kelly and Hellinger, 1986:785; Showstack et al., 1987:785). While there is evidence that such relationships exist for some procedures, such as coronary artery bypass surgery, the evidence is not uniformly persuasive for all procedures studied (Showstack et al., 1987:785). Nonetheless, because of their concerns about cost and quality of care, and increasing limitations placed on clinical research funds to cover the cost of experimental treatments, it is likely that insurers will continue to endorse the concept of designated providers (Schaffarzick, 1987:84). This would suggest that designation of the providers need not be incompatible with the goals of competition. In fact, the financial benefits usually associated with competition may be preserved under a designated provider approach through the direct negotiation of discounts, as in the case of Prudential described above, or through capitated or prospective payment approaches. Although often ignored, HCFA retained an element of competition in its designated center approach through the development of a separate diagnosis related group (DRG) for heart transplantation. Thus, designation does not necessarily undermine the primary objective of competition.

The Duplication of Facilities Hypothesis

The argument is often made that multiple institutions providing the same service in a small area gives rise to increased medical care costs. In general, it has been assumed that the consolidation of facilities reduces costs, although Schwartz and Joskow, among others, have determined that this need not be the case, the case is by no means closed (Schwartz and Joskow, 1980:1449). While the provision of some specialized services may require considerable expenditures for capital equipment and personnel, the start-up

costs associated with other services, such as cardiac transplantation in an active open-heart surgery hospital, may be minimal (Russell, 1986:867; Evans et al., 1984). In this respect, attention must be directed to the marginal added costs associated with a service that is not currently provided, but for which some personnel and facilities are already available on-site.

Advocates of competition are not persuaded that hospital costs necessarily increase as a result of duplicated facilities. Through competition, the costs of services may actually be impacted favorably as multiple facilities compete for the same patient population. If the costs of a service are excessively high at one institution, in comparison with others in the same locale, it is likely that the higher cost institution will be forced to discontinue providing the service, or modify its charges accordingly.

Advocates of regulation are skeptical. They believe that costs are adversely affected by duplicated facilities, and that competition does little or nothing to control costs, or to curtail the provision of services by institutions that charge higher fees for the same service. Not surprisingly, therefore, certificate of need programs are believed to serve both a useful and valuable function by minimizing the opportunities for duplication and associated higher health care costs (Simpson, 1985:1225).

Although far more complex than portrayed here, the duplication of facilities hypothesis has been inadequately addressed. As a result, this hypothesis must, for now, play only a minimal role in debates concerning the merits of, or faults associated with, both the designation or regionalization of specialized health care facilities.

Discussion

In principle, as outlined here, neither the advocates of competition, nor those of regulation, differ as to the value of the concept of designation, if designation is intended to assure quality, cost-effective, medical care. Both sides agree on the need to measure outcomes to fully appreciate the quality of service provided. Also, they each acknowledge a need to empirically determine what factors account for differences in outcomes across providers. Having identified such factors, then both sides agree that designation is appropriate using those criteria to assure quality. There are, however, differences between the proregulatory and procompetition perspectives on several issues related to the concept of designation. These issues include: (1) the value of regionalization, (2) the relationships among quality of care indicators, (3) the role of the patient in the selection of providers, (4) limitations patients may encounter in access to specialized services, (5) the use of a volume criterion to designate providers, and (6) the relationship of duplicated facilities to health care costs. The debates that surround these issues are intense, and the issues themselves are somewhat metaphysical. Therefore, only at the most general level, is agreement possible regarding the value of designation. It is the specifics with which the advocates of the various perspectives disagree.

For many reasons, over the next several years, the concept of designation is likely to become increasingly appealing. Both public and private insurers are intrigued with the concept. It offers them greater control over health care costs, as well as the quality of the services provided. It also offers them an opportunity to more actively participate in the care of

the patients they insure, hence, there is greater reliance on case-management as a corollary approach to cost containment and quality assurance.

Finally, at a time when insurers are concerned about the increased use of investigational procedures in both research and nonresearch settings, designation may well ease the transition of such procedures to therapeutic status (Bunker *et al.*, 1982:620; Schaffarzick, 1987:84; Antman *et al.*, 1988:46). As the research dollar has become constrained, traditional funding sources, such as the National Institutes of Health, have become more hesitant to pay for the clinical care of patients who are the subjects of investigational procedures. Although not often acknowledged, insurers are being forced to "cost-share" in clinical research, and the insurance community is skeptical of the long-term outcome of this practice. Through a system of designated providers, it is likely that insurers will entertain "selective" or "limited" coverage and reimbursement policies, as advocated by Schaffarzick (Schaffarzick, 1987:84). These will be beneficial to patients, as well as providers (Bunker *et al.*, 1982:620; Schaffarzick, 1987:84; Towery and Perry, 1981:59; Bunker *et al.*, 1982:687). Under such a system, insurers may underwrite a portion of the costs associated with investigational procedures in return for data on costs and outcomes. In turn, these data will permit insurers to tailor their policies, and set premiums, thus facilitating innovation in the delivery of health care services, and allowing insurers to become responsive to the needs of their beneficiaries. For example, one procedure that might benefit from this system is unrelated donor bone marrow transplantation (Beatty *et al.*, 1988:714; McCullough *et al.*, 1988:3286).

Clearly, the designation of centers for specialized health care services represents a desirable approach intended to cost-effectively meet the needs of patients for quality health care, while at the same time allowing insurers to conduct their business in a prudent manner. In a very real sense, designation represents a unique partnership among patients, providers, and insurers. At the most general level, the advantages appear to outweigh the disadvantages. Whether this approach is accepted or rejected by all parties concerned, remains to be determined. However, it is important that everyone understands the underpinnings of the designated provider approach. Many of these have been described here.

CHAPTER 18

SOME ETHICAL ISSUES IN TRANSPLANTATION

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CHAPTER 18 SOME ETHICAL ISSUES IN TRANSPLANTATION

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Introduction

Over the past several years much attention has focused on what is commonly referred to as the "ethics of transplantation" (Brock, 1988:86; Caplan, 1985:3339; 1987:10; 1988:42; Kanoti, 1986:43; Mathieu, 1988; Monaco, 1987:1; Simmons and Abress, 1988:691; Younger et al., 1985:321). Although acceptance of ethical analysis in transplantation is relatively recent, ethicists have actively contributed to medicine for many years. Today there is little question that their contributions to transplantation specifically, and medicine more generally, have been both significant, yet controversial. As medicine becomes increasingly technological, often giving rise to uncertainties over the central matter of life and death, ethicists are frequently called upon to intervene in situations where science has accomplished what it can, and morality becomes both unclear and uncertain (Evans, 1983:2047; 1983:2208; Mold and Stein, 1986:512; Churchill, 1987; Daniels, 1986:1380). In short, physicians and surgeons recognize that the dilemma of high technology in medicine includes changes in their role expectations as the providers of care to sick individuals.

Organ transplantation very poignantly illustrates what might be referred to as the "crucible of life and death." With the exception of living-related donor kidney transplantation, a life must end to sustain another. Most often, a personal tragedy has occurred, and an individual has been declared brain dead. The family of the deceased is asked to consider organ donation and, upon their consent, the organs of the deceased are offered for transplantation. This, of course, will be to the delight of another individual and his or her significant others who, in the case of heart and liver

transplantation, is dying with an end-stage disease for which no other treatment option other than transplantation exists.

Unfortunately, there are fewer organs available than are needed by people on the transplant waiting list. Table 18-1 succinctly summarizes the nature of the problem as it exists in the United States today. Since not every patient in need will benefit, a wide array of ethical issues arise. Some of these are what might be referred to as "process" issues. For example, who is the best candidate for transplant? How should transplant recipients be selected? Is it possible to assume that each patient is treated fairly and equitably? Should patients who have received a previous transplant be given an opportunity to receive a second or a third graft? Some process issues are related to organ donation. For example, how can we most effectively improve the supply of donor organs without jeopardizing the moral "fabric" of our existing organ procurement system? Should families be offered financial remuneration for the organs of a loved one? Should we more aggressively approach families concerning organ donation? Should we routinely remove organs from brain dead cadavers without consulting the families involved (Starzl, 1984:1592; Manninen and Evans, 1985:3111)? Clearly, one can identify a myriad of process issues that are central to the whole activity simply referred to as "transplantation."

Another set of issues is less concerned with the "how to" of transplantation, but are organizational in nature. For example, we can evaluate transplantation within the broader perspective of health care. In this regard we might ask, is a disproportionate share of societal resources devoted to transplantation? Would resources committed to transplantation be better spent on preventive health care or maternal and child health care

Table 18-1
The Organ Transplantation Crucible

<u>Organ Transplant</u>	<u>Need Estimates</u>	<u>Number of People Currently On Waiting List***</u>	<u>Supply of Donor Organs</u>
Kidney Transplants (Cadaveric)	13,703*	13,703	8,000
Heart Transplants	14,500**	981	1,600
Liver Transplants	9,500	552	2,000

NOTES

- * On dialysis awaiting transplant
- ** Number of people who die annually of conditions for which transplantation is indicated
- *** United Network for Organ Sharing (Richmond, Virginia) waiting list (October, 1988)

initiatives? Should ability to pay be a consideration in determining who should benefit from a transplant? Should age be a consideration in determinations of who will maximally benefit? What is the value of a human life in our society? All these issues are complex, and can hardly be dealt with in the abstract. We must surely adopt a wider perspective to appreciate the complexity of these issues (Evans, 1987:63; 1986:91).

While the foregoing distinction between process and organizational issues is useful, it is readily apparent that the two sets of issues overlap. Therefore, in the remainder of this chapter we will focus on general topics, and incorporate appropriate discussion of both the process and organizational issues. The primary topics are as follows: (1) organ procurement, (2) patient selection, (3) cost and reimbursement, (4) quality of life, and (5) resource allocation.

Organ Procurement

In general, it is believed that there are many more potential organ donors than the procurement system is able to access. Based on our research at Battelle, we have either developed, or identified, various ranges of estimates (Evans et al., 1984; 1984:57; 1986:1892; Evans, 1984). These estimates are summarized in Table 18-2. Comparing these estimates with those in Table 18-1, it is evident that much remains to be done to meet the need for donor organs in the United States.

Estimates such as those in Table 18-2 have given rise to much discussion as to how we can make our procurement efforts more successful. Some people have suggested that much more could be done with organ donor cards (Overcast et al., 1984:1559). Yet our research indicates that donor cards are

Table 18-2
Potential Donor Organ Supply Estimate

<u>Organs</u>	<u>Potential Organ Supply Estimate</u>		
	<u>High</u>	<u>Moderate</u>	<u>Low</u>
Kidney	92,000	40,000	27,000
Heart	18,400	8,000	5,400
Liver	23,000	10,000	6,750

an effective means by which to educate people, but relatively unproductive with respect to actual donors. Routine inquiry and required request legislation has been passed at both the state and federal levels with little real benefit realized at this time (Caplan, 1984:981). Presumed consent has been advocated, but only about five percent of the United States population feels comfortable with this concept (Starzl, 1984:1592; Manninen and Evans, 1985:3111). Others have argued that anencephalics should be considered for organ donation, but the ethical issues surrounding the definition of death seem quite formidable at this time (Harrison, 1986:1383). Public education efforts could be stepped up, however, it is apparent that the public is sufficiently aware of the need for donor organs. Xenografts have some potential but, once again, significant immunological and social barriers must be overcome. Today, in light of the foregoing, much greater attention is focusing on professional education as the primary means to improve the supply of donor organs. While this is, indeed, a fertile area in which to concentrate our efforts, it is apparent that the task at hand is by no means easy.

Upon surveying current efforts to enhance the supply of donor organs, ethicists would express concern that these efforts not violate any fundamental beliefs--religious, moral or otherwise--to which people subscribe (National Task Force on Organ Transplantation, 1986). To do so, may well prove counterproductive because of innate concerns people have about life and death. It is in this regard that anencephalic organ donation is viewed by many as problematic. A redefinition of death would be required to enable the routine removal of donor organs from anencephalics. This may simply be too significant a step to take at this time.

Patient Selection

The selection of transplant recipients is without a doubt the most complex issue in organ transplantation (Brock, 1988:86; Caplan, 1987:10; Evans and Yagi, 1986). In addressing this issue, several questions immediately come to mind, including the following:

- What is the proper role of clinical and social criteria?
- What role should age play?
- Is quality of life an important consideration?
- Is it possible to empirically validate all criteria used to select patients?
- What is the appropriate timing of transplant?
- Should a retransplant be performed, given that another patient will be denied a transplant?
- Do the outcomes of retransplantation justify this course of action?
- Is the use of an artificial device warranted to "bridge" patients until a donor heart becomes available?
- Because of complications associated with current devices, is it not likely that bridged patients will be given priority over human heart candidates?

The foregoing does not exhaust all the patient selection issues that transplant teams have had to address. They do, however, illustrate the range of issues that have been confronted.

While there are no fixed rules as to what are the right clinical and social criteria, there does appear to be a reasonable consensus within the transplant community as to what factors are key in the selection of patients (Evans, 1987:13; Evans and Manninen, 1988:781; 1987). Clinical criteria are of

primary importance, and social criteria play a minor role. In fact, we have found that transplant teams routinely select patients according to criteria with which the public agrees. Table 18-3 summarizes the results of a national survey of the general public concerning the use of specific medical and social criteria in the selection of transplant recipients (Evans and Manninen, 1987). As is apparent, the public generally disagrees with the use of social criteria.

At this point in time it is difficult to prognostically validate all of the criteria used to select transplant recipients (Evans and Yagi, 1986). Although it is evident that certain patients are "at risk" given various characteristics, such as advancing age or diabetes, no firm evidence has been amassed to categorically reject patients for transplant. Even AIDS has been disputed as an absolute contraindication to transplantation.

The timing of transplant is a complicated issue (Stevenson et al., 1987:267). While it could be argued that the sickest patients are not necessarily the best candidates for transplantation, the national organ procurement and distribution network--the United Network for Organ Sharing (UNOS)--assumes otherwise (Starzl et al., 1987:3073; Rapaport, 1987:3118; Salvatierra, 1988:1329). One could, however, reasonably argue against this policy. The sicker the patient, the more uncertain the outcome and, thus, the more likely that another patient could have benefited to a greater extent. This is an area that will require greater attention in the future.

Retransplantation raises several questions about fairness and equity (National Task Force on Transplantation, 1986). While the medical and surgical team is committed to the care of all patients, the retransplanted patient seems to have an unfair advantage. For each organ a retransplant

Table 18-3

Public Opinion Concerning the Use of Specific Medical and Social Criteria in the Selection of Transplant Recipients

	<u>Strongly Agree</u>	<u>Agree</u>	<u>Disagree</u>	<u>Strongly Disagree</u>	<u>No Opinion</u>
Preference should be given to younger rather than older people	10.6	46.2	28.7	2.9	11.6
Preference should be given to the sickest patients	11.6	59.5	18.4	0.9	9.7
Preference should be given to U.S. citizens over <u>all</u> other patients	9.3	42.4	35.5	3.7	9.1
Preference should be given to those who can afford them	0.5	7.7	61.4	25.6	4.9
Preference should be given to people with a strong religious background	0.2	5.2	68.3	21.4	4.9
Preference should be given to people who do <u>not</u> drink alcohol	1.6	17.8	62.5	11.1	7.1
Preference should be given to people who are most likely to survive and benefit	17.3	66.0	10.9	0.5	5.4
Preference should be given to those who are most likely to be able to return to their usual work and/or household activities	10.2	61.7	19.6	1.2	7.3
Preference should be given to people who do <u>not</u> smoke	2.7	23.6	56.9	7.8	9.0
Preference should be given to people who live a "healthy" lifestyle	2.8	37.9	44.8	4.5	10.0

recipient receives, another patient is denied an opportunity for transplant. Over time it is likely that our policies concerning retransplantation will have to be refined, perhaps limiting individuals to no more than two transplants. This does appear to be justified clinically, as the probability of a successful transplant declines with each successive transplant.

Mechanical devices for bridging patients for cardiac transplantation seem to have fallen out of favor, perhaps as a result of the great uncertainty associated with the procurement of an acceptable heart (Joyce et al., 1986:229; Griffith et al., 1987:130; Loisanse et al., 1987:281; Pierce, 1988:891). While some devices have served this purpose well, and some teams have become quite successful in bridging very sick patients, the continued use of mechanical devices for this purpose is likely to be very limited in the future. It is noteworthy, nonetheless, that one major criticism of the bridging procedure--that such patients are moved to the top of the waiting list--is incorrect. Patients who are bridged are by definition sufficiently sick to be at the top of the list already. The mechanical device prolongs their life, it does not render them sicker and, thus, more worthy of heart transplant than they were previously.

There is little doubt that over the past two years much has been done to assure transplant candidates that they will be treated fairly and equitably by the national organ procurement and distribution system. As the policies of the United Network for Organ Sharing have been refined, patients have fewer reasons to be suspicious of the policies and procedures by which organs are procured and distributed in the United States. Fairly sophisticated distribution systems have been implemented at the local, regional, and national levels to assure that the most needy transplant candidates are given

the most ready access to the donor organ procurement system. This system is a relief to the patient, the transplant team, and the health care policy makers of the United States.

Cost and Reimbursement

Heart and liver transplantation procedures are expensive according to any standard (Evans, 1987:61; 1986:91; 1985:129; 1986:603; 1987:63; 1986:425). End-stage disease, regardless of its etiology, is expensive to treat, as is all catastrophic disease. Today, the total first year costs associated with a heart transplant can easily exceed \$100,000, and a liver transplant, \$200,000. While many private insurers now consider heart and liver transplants to be therapeutic (no longer experimental), some public insurers, namely state Medicaid programs, have begun to reconsider their policies (Evans, 1986:425; Welch and Larson, 1988:171; 1988:1420). In some states, coverage has been suspended. Not surprisingly, patients without insurance, as well as those with inadequate insurance, are finding it difficult to gain admission to transplant centers. Many transplant centers now require assurance of insurance payment, or an actual down payment, often in excess of \$100,000, before a patient will be placed on the waiting list for a transplant.

For many patients, the transplant "system" is unfair, particularly when it operates as described here. It is not unusual for patients without the necessary financial means to be denied access to a transplant. For example, several years ago the National Task Force on Organ Transplantation determined that 78 percent of the transplant surgeons in the United States were influenced by an individual's ability to pay when considering a patient for transplant (Goeken, 1985). Moreover, 38 percent of the surgeons surveyed

said that ability to pay for immunosuppressive medications influenced their selection of cardiac transplant recipients.

Public opinion data clearly show that the general public is opposed to the use of economic criteria in the selection of transplant candidates (Evans and Manninen, 1988:781; 1987). Over 80 percent of the public agrees with the following statement, "Medical need, not social or economic factors, should be the only criteria used to select transplant recipients." Only 8.2 percent of the public feels that "preference should be given to those (people) who can afford them (transplants)" (see Table 18-3). Finally, over 88 percent of the population is "most concerned that donor organs are distributed as fairly and equally as possible." Obviously, there is absolutely no evidence that the general public will support economic discrimination when it comes to access to transplantation.

Despite their unwillingness to allow economics to play a role in the selection of transplant candidates, the public cannot ignore the significant costs associated with transplantation. In one way or another, we all bear the burden of higher health care costs. Either taxes are raised to help insure a growing segment of the under-insured or uninsured portion of the population, or private health care insurance premiums are increased to cover added health care costs, or both. Alternatively, private insurers can increase deductibles and co-payments as well (Health Insurance Association of America, 1985). The underlying concept here is simple: if we want increased health care benefits, we must be prepared to pay for them. While numerous attempts have been made to increase the efficiency with which health care services are delivered, in an effort to reduce total expenditures, it has become clear that such efforts have fallen short of their mark (Angell, 1985:1203). Either

services must be reduced, or taxes and insurance premiums increased to cover costs. Over the past several years many major health insurance companies, including the Blue Cross and Blue Shield Association, have sustained heavy losses. As a result, this year (1989) health insurance premiums are expected to increase an average of 30 percent. However, it is unlikely that transplantation has contributed significantly to this increase.

Increasingly, as people are unable to afford private health insurance, the burden placed upon public insurers, primarily Medicaid programs, will become even more significant than it is already. This, of course, will lead states to cut benefits or to increase taxes, neither alternative being particularly palatable at this time. However, when push comes to shove, it is likely that certain high cost benefits may be curtailed in order to make available services that are viewed as being more cost-effective. This is basically what occurred in the State of Oregon (Welch and Larson, 1988:171). If people object to this action, they should be prepared to give up other nonhealth related services, or to pay higher taxes.

Despite efforts to underscore the resource allocation dilemma inherent in organ transplantation, it is noteworthy that total Medicaid expenditures for transplant services have been minimal. As reported by the Intergovernmental Health Policy Project (1988), the relative distribution of the reported cost to Medicaid in fiscal year 1987 in descending order of magnitude was as follows:

Liver transplants:	\$7.3 million
Bone marrow transplants:	\$6.9 million
Heart transplants	\$3.6 million
Kidney transplants:	\$3.1 million

Cornea transplants:	\$1.1 million
Heart-lung transplants:	\$0.4 million
Pancreas transplants:	\$0.1 million

Thus, as is apparent here, very little is currently being spent by Medicaid programs for the provision of transplant services. Private insurers have also had a similar experience, leading some to speculate that actual transplant-related costs constitute little more than "rounding error" in total insurer expenditures.

Ethically, what has been described here is rather confusing. While people may be unwilling to allow for economic discrimination, they may, in the end, have little alternative. As people recognize that both public and private insurance is a cooperative cost-sharing endeavor, they may begin to reconsider the types of coverages they believe are necessary for them, as well as other people. Perhaps the underlying ideology is best characterized by the words "willingness to pay" (Culyer, 1982:107). If people have the resources and are willing to expend them accordingly, then transplantation is their prerogative. In a sense, transplantation is considered in the same class as cosmetic surgery, although there is one serious difference--transplantation holds the promise of saving lives, whereas cosmetic surgery has the potential to make life more appealing for oneself or others.

While this analysis may seem emotionally cold-hearted, given the altruism that underlies the transplant enterprise, there are certainly other analogies apparent within the existing health care system. For example, the quality of the health care services available to the wealthy and the poor is vastly different. The local county hospital may offer adequate health care services, but the quality and range of services available at a private institution that

caters to the wealthy may be far superior to those of the county hospital. In short, not everyone has equal access or is treated equally by the complex health care delivery system that exists in the United States (Aday et al., 1984; Iglehart, 1985:59; 1982:836). Death can conceivably be the outcome of having chosen, or been transported to, an inferior hospital for medical care.

Ultimately it seems unusual that we insist that everyone, regardless of economic status, be given equal access to transplantation when we are unable to even guarantee access for all to other less sophisticated services. It would seem that we should first direct our attention to other areas in medicine where more can be accomplished. Having said this, however, we recognize that this necessarily implies that the wealthy and the insured be given priority in access to transplantation. An alternative might be to "tax" those patients who are able to pay in order to permit some uninsured patients to have access to transplantation. For example, physicians and surgeons may not be allowed to charge fees for uninsured patients, or a surtax is levied on each paying patient to create a fund for the uninsured. While in principle these options are attractive, in practice they may well be difficult to implement.

Quality of Life

If nothing else, our limited experience with the total artificial heart (TAH) has thrust upon us a new appreciation of the quality of life concept. As the media made us aware of the trials and tribulations of Barney Clark, William Schroeder, and other TAH recipients, we increasingly began to ponder when our own quality of life would be unacceptable and death a better alternative. Of course, this same question was asked of the first patients who were placed on maintenance hemodialysis. How was it that a patient

could undergo 40 hours of dialysis each week and still have a will to live? Even today, during an era when medical technological developments have become increasingly advanced, we find that these same questions are contemplated. Is life worth living, and at what point will it be so compromised that the hastening of death would be attractive. In a recent report, Roberts and Kjellstrand indicate that of the 1,766 hemodialysis patients they studied, 1.5 percent preferred death to the stress of dialysis (Roberts and Kjellstrand, 1988:181). In this regard, it is interesting to note that 2.6 percent of dialysis patients voluntarily withdraw from dialysis within 18 months of starting dialysis (see Table 18-4).

In our many studies on the quality of life of transplant recipients, we persistently find that on subjective quality of life measures (i.e., well-being, psychological affect and life satisfaction) patients do exceptionally well (Evans, 1987:61; 1986:91; 1985:129; 1986:603; Evans et al., 1985:553; 1985:1579). On the objective indicators, however, patients uniformly do poorly. They often have a wide range of physical limitations, remain unemployed even though able to work, and their health status, although vastly improved since transplant, is subject to uncertainty, owing largely to chronic immunosuppression. Despite these findings, on average, transplant recipients fair well posttransplant.

What is surprising, unfortunately, is how few transplant recipients are fully aware of what their future will hold. Many view transplantation as a cure for a terminal condition, rather than a treatment that converts a terminal disease to a chronic condition. Patients often do not anticipate the limitations they will endure and are frequently inadequately informed of the rigors of immunosuppression. Many are not prepared for the occasional

Table 18-4

Percent of Patients Voluntarily Withdrawing
from Dialysis Within 18 Months of Starting Dialysis

<u>Age Group</u>	<u>Percent of Patients</u>
0-14 Years	0.1
15-24 Years	0.1
25-34 Years	0.8
35-44 Years	0.8
45-54 Years	1.1
55-64 Years	2.0
65-74 Years	4.1
75 Years or Older	7.8
All Persons	2.6

SOURCE: Eggers, Health Care Financing Administration, 1989.

setbacks that may befall them as they become long-term survivors. Others have difficulty coming to grips with changes in body image that may accompany the routine administration of both prednisone and cyclosporine.

While the majority of patients are happy with their lives, they, perhaps, have unusual notions as to what constitutes an adequate quality of life. Each patient who has looked into "death's eye," and survived a transplant, may in fact expect less of life than people who have not had a near-death experience. This is certainly true of patients who have survived cancer and learn to live each day as if it were their last. The "little things" that previously bothered them are somehow small in the grand scheme of human experience. The same is true of transplant recipients, at least initially. However, as time passes and the patient embarks upon a relatively stable posttransplant course, their expectations change. They want more out of life, and realize that they may have little time to accomplish their goals. Transplant recipients may become less tolerant of friends, family, and caregivers. While this may be alarming to those around the patient, it is, we think, the outcome of a new found appreciation of life, and the very uncertainty that characterizes much of human existence.

While suicide is relatively infrequent among transplant recipients, it does occur, often in response to protracted medical complications associated with the transplant. Over time, as the side-effects of immunosuppressive drugs take their toll, patients may begin to, once again, contemplate the death experience they previously avoided. Life may become more difficult to live as the uncertainties become more profound. Patients typically respond in several ways: (1) they may be satisfied with the period for which their lives have

been extended, (2) they may be angry that they have to again face death, and (3) they may hope that death can again be avoided.

Regardless of how it is assessed, the quality of life dilemma transplant recipients face is real. Patients must be well-informed prior to transplant as to what they can expect posttransplant under ideal as well as compromised conditions. Too frequently patients are led to believe that the ideal is the norm when, in fact, this is not the case. The transplant experience can be envisioned as points along a continuum. At one end we have the ideal--the heart transplant recipient who is discharged from the hospital in 10 days without a complication or a hint of rejection. At the other end of the continuum is the patient who is hospitalized in an intensive care unit for 180 days, with many complications related to surgery as well as immunosuppression, and dies prior to discharge. The ideal patient has an excellent quality of life prognosis, while the patient who died prior to discharge undoubtedly had a deplorable "quality of dying" experience. Hindsight would suggest that the patient who died would have been further ahead if transplantation had not been offered as a treatment alternative. This is primarily because the dying experience was protracted due to "clinical cascade" (Mold and Stein, 1986:512). To be sure, somewhere between these two extremes is the "usual" transplant patient experience. The problem for the transplant community is to make patients and their families aware of the variations that occur in the transplant experience. Transplantation is a highly unpredictable experience and, as such, a patient must have considerable social and clinical resources upon which to draw. If a patient is not fully apprised of what to expect, an average experience could

easily become an unmitigated disaster that the patient and his or her family may regret having endured. Such risks and uncertainties are, of course, common to many other surgeries and therapies, such as major heart surgery and chemotherapy.

Resource Allocation

Full treatment of the resource allocation and rationing issue as it applies to transplantation is well beyond the scope of this chapter (Evans, 1983:2047; 1983:2208; 1987:61; Baily, 1988:198). It is, nonetheless, important to point out that transplantation does underscore the underlying differences between the concepts of allocation and rationing. First, donor organs are essentially rationed among potential transplant candidates. Not every patient in need will get transplanted and, as a result, some patients will die. Second, the financial resources available to cover the costs associated with transplantation are, to some extent, finite and, therefore, what constitutes the appropriate use of these resources is debated among insurers and policy analysts (Baily, 1988:198). In short, a question of resource allocation arises. As noted previously, could the resources committed to transplantation be better used to provide other less costly, more cost-effective health care services?

The rationing issue has already been addressed to some extent during the discussion of the patient selection dilemma. The resource allocation issue has only been acknowledged superficially. In this regard, we would be remiss if we did not point out that, in the grand scheme of the resource allocation debate, transplantation has been treated unjustly (Evans, 1986:91). Transplantation is not a weird and unusual form of treatment for patients dying with end-stage disease. In effect, transplantation should be

likened to the treatment of other "catastrophic diseases." One can easily think of many examples of costly diseases and treatments that have not been singled out for "negative" attention. Today, the treatment of AIDS may be the single best example of a costly condition to treat with relatively little net benefit to the patient or society (see Table 18-5) (Scitovsky and Rice, 1987:5; Andrulis et al., 1987:1343; Arno, 1987:1376; Lafferty et al., 1988:949; Bloom and Carliner, 1988:604; Scitovsky, 1988:32). The intent here is not to be moralistic, but simply to underscore the fact that as our population ages, the prevalence of catastrophic disease will increase, as will expenditures associated with the treatment of these conditions. In 1987, 11.1 percent of the gross national product was devoted to health care, up from 10.7 percent in 1986.

If the allocation issue is as significant as many contend it is, it is unfortunate that we select for scrutiny the treatment of one or two conditions to which public resources are allegedly being diverted excessively. In this regard, one should bear in mind that transplant costs are severely constrained by the availability of donor organs (Evans et al., 1986:1892). Costs will be incurred only to the level that donor organs are procured and transplanted. This constraint is real, and raises another important ethical question. If we are unprepared to pay for transplants, should we continue our efforts to improve (increase) the supply of donor organs? As we observed elsewhere, people more readily accept the lack of donor organs as the reason a patient may not receive a transplant than they do the lack of funds to pay for the procedure.

Rather than single out transplantation as a major "culprit" behind the rising cost of health care, we need to provide a forum for a more general

Table 18-5
AIDS Treatment Costs

<u>Life Expectancy</u>	<u>Per Case Lifetime Medical Care Costs</u>
N/A	\$ 23,000
24 Weeks	\$ 36,000
56 Weeks	\$168,000
78 Weeks	\$ 77,000
32 Weeks	\$ 32,000
N/A	\$ 43,000 - \$115,000
N/A	\$ 55,000
N/A	\$ 35,054

N/A = not available

SOURCE: Bloom and Carliner, 1988:604.

discussion of the cost of medical care, the components of these costs, the role of catastrophic illness in the delivery of health care services, the opinion of the public with respect to high cost medical care, and options available to directly address the resource allocation dilemma (Crawshaw *et al.*, 1985:3213). By limiting our attention to transplantation we, unfortunately, avoid the larger issue and create problems of equity and fairness.

Some observers have argued that resource allocation and rationing decisions are not necessary, if we provide only the type and level of care the patient actually requires, however, we remain unpersuaded (Evans, 1983:2047; 1983:2208; Angell, 1985:1203). We do not think that discontinuing ineffective treatments, or eliminating those that have little or no value, will conserve sufficient resources to enable us to meet all our health care needs. Moreover, we do not believe that it is simply the overuse of little technologies that adds substantially to the cost of health care in the United States. Regardless, of the explanation for the high cost of health care, the demands being placed upon the health care delivery system are considerable. It will be necessary to make difficult choices (Cohen, 1986). However, these choices must be made systematically, based upon the best available information, with an eye towards both costs and effectiveness.

Comparatively, transplantation offers benefits that are worth the costs, given other accepted forms of "therapy" for other catastrophic conditions (Evans, 1987:61). This is the broader perspective we alluded to at the outset of this chapter. In effect we must ask, how does transplantation fit within the grand scheme of health care? What will the future hold? Will costs increase and benefits decrease as patient selection criteria evolve? Will donor supply increase to create a resource allocation problem of immense

proportions, while the resource rationing problem is minimized? These, indeed, are some of the issues of the future, all being central to the debate concerning resource constraints.

Discussion

As medical technology has become increasingly sophisticated, the ethics associated with the practice of medicine have become a matter of much debate. This chapter has briefly considered several issues that are of significance to any discussion pertaining to the ethics of transplantation. Ethicists have offered some unique perspectives on these issues, but have, at times, been insufficiently informed about the clinical aspects of transplantation. As a result, their analyses can be misleading. Over time, however, as ethicists become more familiar with transplantation, the situation will hopefully improve. While it is unnecessary for ethicists to be a part of the team, access to a consulting ethicist may be of some benefit to the team.

Unfortunately, because of their ill-defined role, and the medical profession's lack of familiarity with medical ethics, ethicists have been elevated to a status that exceeds their utility. Ethicists do not offer unequivocal solutions to the complex moral problems associated with transplantation. They simply offer an additional perspective--a perspective that often reflects the disciplinary background of the ethicist whose consultation is sought. Some ethicists have trained in philosophy, others in religious studies, and still others have a social and behavioral science background. As a result, ethicists have a variety of opinions and perspectives, and a consensus is no more likely to emerge among ethicists than among physicians and surgeons on any single issue. Moreover, because

of their lack of clinical experience, many ethicists are not easily integrated into the clinical decision-making process. In fact, during clinical conferences, ethicists may be detrimental to the proceedings.

As implied here, medical ethics has significant limitations when conflict resolution is required among members of the transplant team. These limitations apply to all the issues reviewed above--organ procurement, patient selection, cost and reimbursement, quality of life, and resource allocation. To say the least, the ethical dilemmas the transplant team faces can be frightening. However, as transplantation is increasingly being forced to be publicly accountable, the satisfactory resolution of all ethical issues becomes of paramount importance. In this regard, medical ethicists may be of some help, but they will not be the savior that medicine now seeks.

CHAPTER 19

OTHER ASPECTS OF TRANSPLANTATION AND A REVIEW OF RECENT ACTIVITIES

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CHAPTER 19 OTHER ASPECTS OF TRANSPLANTATION AND A REVIEW OF RECENT ACTIVITIES

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Introduction

This report cannot possibly do justice to all aspects of kidney transplantation. The field of transplantation is simply too broad and varied. There are, however, a number of issues that require further consideration in anticipation of future developments in the treatment of ESRD. Therefore, this chapter will focus on the need for kidney transplantation, the availability of donor organs, and the integrated treatment of ESRD. With this information in hand, we will then review several recent activities that are intended to address various problems associated with transplantation and the provision of services to patients with end-stage renal disease.

The Need for Kidney Transplantation

It is appropriate to distinguish between the need and the demand for kidney transplantation. An estimate of the need for transplantation can be derived by determining how many people in the population have renal failure and are suitable candidates for transplantation. Many of these patients may already be on dialysis, and others may be in the advanced stages of renal failure and could conceivably benefit from preemptive transplantation. The demand for transplantation is revealed by the number of people on the national waiting list for transplantation. At this time there are over 14,000 people awaiting kidney transplantation. Assuming that all patients with renal failure who could benefit from a transplant are on the waiting list, the need and the demand for transplantation are equal. If, however, some patients prefer dialysis to transplant, and others are conceivably sequestered by nephrologists, the need for transplantation is greater than demand.

The need for transplantation is entirely a function of patient selection criteria. As patient selection criteria become increasingly liberal, a growing number of patients could potentially benefit from transplantation. For example, diabetics as well as elderly patients are no longer excluded as candidates for transplantation. As noted by Keown and Stiller (1988:s145), analysis of outcome by decade "... indicates no increase in mortality up to the seventh decade and, in most centers, elderly patients are now routinely considered for transplantation." "Diabetes they suggest remains a risk factor, producing a "... decrease of approximately 10 percent in both patient and graft survival when compared to nondiabetes patients." In addition, sensitization is a major risk factor for transplantation. Patients who are highly sensitized (greater than 75% of the target panel) have their primary graft survival reduced to 50 percent and subsequent graft survival to 29 percent (Keown, 1985:328).

With greater experience, patient selection criteria for kidney transplantation will probably be relaxed further, and the need for transplantation will increase proportionately. The demand for transplantation will increase concomitantly as well. Whether all patients who could benefit from transplantation are placed on the waiting list remains a matter of some concern. Periodic reports suggest that some patients who could benefit from transplantation fail to get on the waiting list for racial, economic, or other factors (Held et al., 1988:2594). Unfortunately, many of these reports are based on a poor conceptualization of the problem, questionable data, inappropriate analysis, faulty interpretation, or some combination of the foregoing. What we do know is clear: once patients are on the waiting list, they are treated fairly and equitably according to procedures developed and

implemented by the United Network for Organ Sharing (UNOS). In short, if discrimination is taking place, it is occurring before patients are put on the waiting list.

Availability of Organs

As outlined in this report, donor kidneys are simply unavailable in the quantity required. In 1987 there were approximately 4,000 cadaveric donors in the United States. Since each donor is potentially the source of two kidneys, this means there were about 8,000 donor kidneys available for transplantation. In addition, approximately 20 percent of all kidney transplants in the United States are performed using a living related donor. While efforts are being made to improve organ donor supply, these efforts have met with limited success. There is little evidence, for example, that required request legislation at both the state and federal levels has yet had a positive impact (see Andersen and Fox, 1988:65; Caplan, 1988:34; Martyn et al., 1988:27). Nonetheless, research continues to show that there are more donors available than are being accessed by the present procurement system (Bart et al., 1979:455; 1981:379; 1981:383; Council on Scientific Affairs, 1981:2157). In fact, our research suggests that between 17,000 and 92,000 donor kidneys could be available annually. Actual supply varies depending upon public opinion, donor selection criteria, and other structural variables that facilitate or hinder the procurement of organs.

Alternatively, we must also recognize that various efforts intended to save human lives may actually have a "donor-sparing" effect. In this regard reduced speed limits, motorcycle helmet laws, child restraint seat laws, drunk driving laws, handgun laws, and more proficient trauma care may all diminish

the supply of organ donors (Agran and Wehrle, 1985:128; Chorba et al., 1988:3593; Decker et al., 1984:2571; Decker et al., 1988:3604; Editorial, 1988:159; Fuller et al., 1986:614; Goldbaum, 1987:1473; Guerin and MacKinnon, 1985:142; Hingson et al., 1988:548; Latimer and Lave, 1987:183; Sanders and Dan, 1984:2613; Steed, 1988:3651; Taggi, 1988:182; Williams and Wells, 1981:163; Williams and Lund, 1986:1438; Williams et al., 1987:1450). Moreover, the AIDS epidemic may have the single greatest impact on the procurement of donor organs, since the Centers for Disease Control considers HIV positivity to be an absolute contraindication to organ donation.

Therefore, as the demand for kidneys reaches its highest level, the supply of donor organs is leveling off at best and, at worst, there may actually be a net decrease in the number of donors in the years to come. This, indeed, is cause for concern, as many patients with renal failure have become convinced that a kidney transplant is in their future. Patients have high expectations given the results of renal transplantation, but at a time when actual procurements are insufficient to meet the growing demand.

An Integrated Approach to ESRD Management

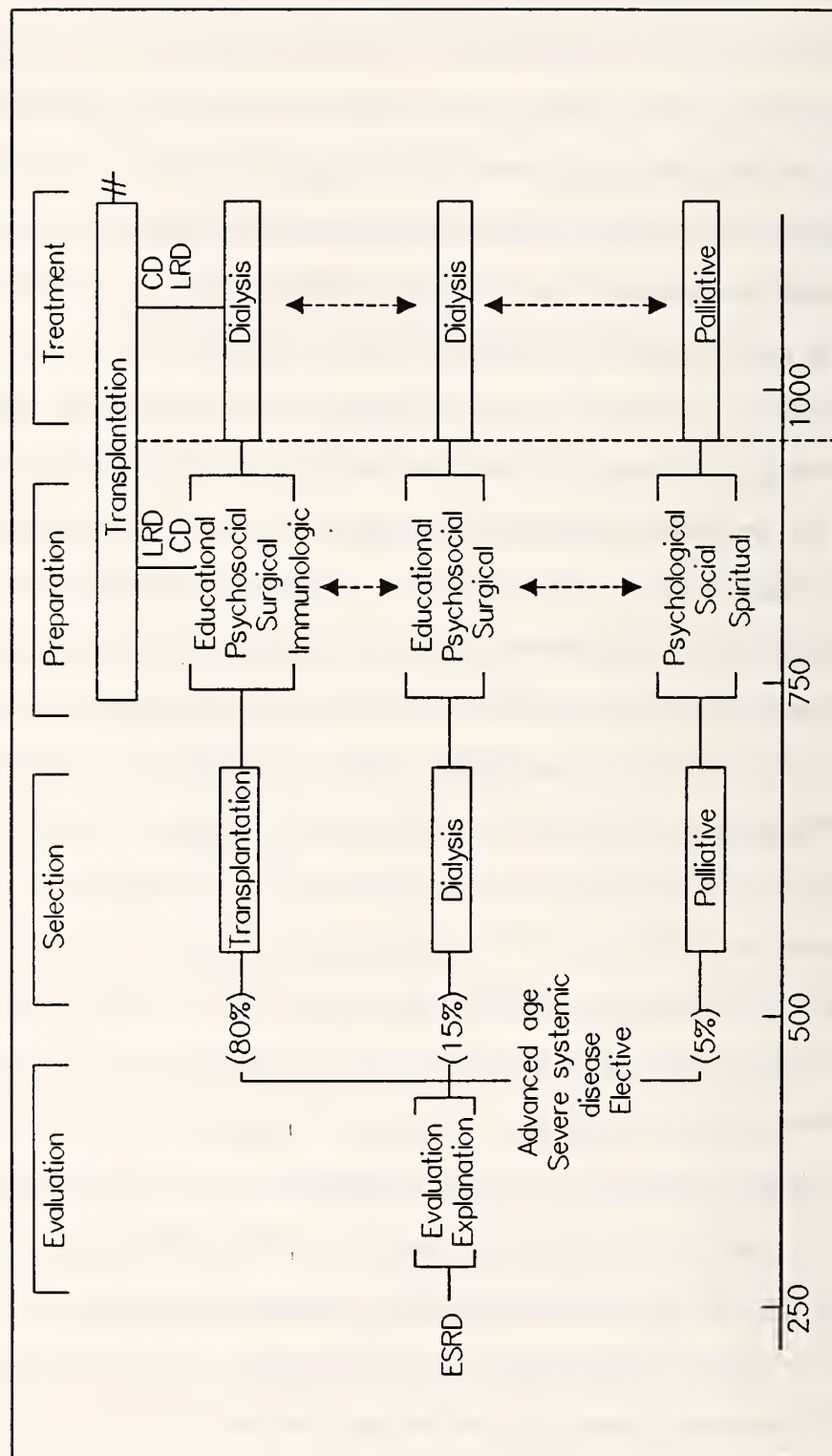
The foregoing data, as well as the overall results of this report, indicate that there is a clear need for an integrated approach to the management of patients with renal failure. One such approach has been developed by Keown and Stiller (1988:s145). In presenting their approach, Keown and Stiller acknowledge that it is necessary to meet the diverse needs of many individuals including the patient, the health care delivery team, and society as a whole. The patient is, of course, concerned that

they be provided with high quality care that best manages their renal failure. The health care delivery team shares this concern, but also wants to provide care that is intrinsically of interest to them for both professional and academic reasons. Finally, since society eventually "pays the bill," it is important that the care is cost-efficient with the potential to maximally rehabilitate the largest number of patients. As indicated, the concerns expressed here are shared by all parties involved. Patients, too, for example, have an interest in their rehabilitation and reintegration into society.

Ideally, it is highly desirable if dialysis can be avoided for the majority of transplant recipients. By doing so, the progressive deterioration of the renal failure patient is obviated and rehabilitation is much more likely to occur, and in a shorter period of time. Unfortunately, preemptive transplantation is only feasible for patients with a suitable living-related donor, or in limited cases where early cadaveric transplantation is possible. As pointed out by Keown and Stiller (1988:s145), achievement of the goals outlined above "... necessitates a fully integrated program for the management of ESRD where both transplantation and dialysis are utilized with maximum efficiency." The program they have in mind, along with appropriate therapeutic decision points, is identified in Figure 19-1.

Once a patient is identified as having irreversible renal failure, the available treatment modalities are discussed with the patient and their family in an effort to establish an optimal treatment plan. A small proportion of patients, perhaps one percent, may be referred for palliative care primarily because of advancing age and coexistent systemic disease that severely limits the prognosis for either dialysis or transplantation. These patients may opt out of treatment, recognizing that the benefits they may derive will be small.

Figure 19-1. A goal oriented approach to the management of kidney failure.



Other patients with persistent and uncorrectable sepsis, noncutaneous or metastatic malignancy, or severe organic disease which may unacceptably increase the risks of surgery and immunosuppression or greatly reduce expected survival, are, perhaps, better suited for maintenance dialysis.

However, for the majority of patients, estimated by Keown and Stiller (1988:s145) to be 75 percent, transplantation is truly the optimal form of therapy. For these patients, medical and surgical preparation is initiated, accompanied by psychosocial and educational support. If present, ischemic heart disease may require attention, and bilateral nephrectomy may be indicated for persistent upper tract infection. Otherwise, bilateral nephrectomy is rarely performed today. At this point, elective transfusion may be employed, with careful attention directed to the development of anti-HLA antibodies. Upon completion of recipient preparation, the search is undertaken for an appropriate donor, beginning with close family members and extended to more distant familial or spousal donors, where a successful outcome can be anticipated in 90 percent of cases (Belzer et al., 1984:26). If a living donor cannot be identified, the patient is placed on the waiting list for a cadaveric donor. For the majority of these patients, dialysis will be required for at least a short period of time. Ultimately, the transplant is performed when a donor graft becomes available.

Clearly, the foregoing approach to the management of renal failure is highly integrated. All therapeutic options are presented to the patient with incipient renal failure, and a rational long-term management strategy is devised based on clinical status, psychological stability, convenience, and acceptability. Dialysis is normally used as a short-term procedure pending the availability of an organ donor, thus facilitating optimal correction of the

uremic state. Early rehabilitation and social integration are actively pursued to minimize disease impact while maximizing quality of life.

Unfortunately, in the United States there is no overall plan for the management of renal failure. Each treatment facility, whether dialysis or transplant, pursues its own treatment plan which is believed to be in the best interest of the patient and the health care team. Society's interests are more or less represented by the Health Care Financing Administration (HCFA) which, through various reimbursement methodologies, attempts to provide incentives for the cost-effective management of renal failure. For example, transplantation is generally believed to be the treatment of choice. Among the various dialysis modalities, those that can be accomplished in the home setting, or on an ambulatory basis, are thought to be preferable for cost as well as patient benefit reasons. No effort is made to make certain that all patients for whom transplantation is indicated are placed on the waiting list. This would, of course, be an onerous regulatory task. Moreover, since all the available donor kidneys are being used, there is little to be gained by lengthening the transplant waiting list.

Interestingly, three efforts have been initiated that may well have important implications for the future treatment of renal failure in the United States. These are: (1) the United Network for Organ Sharing, (2) the United States Renal Data System, and (3) the Institute of Medicine's (IOM) initiation of a study on the treatment of end-stage renal disease. Each of these efforts is briefly described below.

Recent Developments of Relevance to the ESRD Program

Since the formation of the National Task Force on Organ

Transplantation, much attention has been focused on the provision of transplantation services in the United States. Whereas in the past there has been minimal involvement of the government in the affairs of the transplant community, this has changed rapidly. Many recent efforts have been intended to better organize transplant activities and to monitor them through appropriate data collection and analysis. Only time will tell whether these activities can meet their challenge, and whether the transplant community is willing to accept increased intervention on behalf of government officials.

In the review that follows, we will only highlight the major thrusts of the three separate activities identified above. With the exception of UNOS, the other two activities are in the early stages of development and implementation. In all of the activities, however, there are some common threads that engender both cooperation as well as competition.

The United Network for Organ Sharing

Among its many recommendations, the National Task Force on Organ Transplantation included the following pertaining to the formation of a National Organ Procurement and Transplantation Network (OPTN):

The Task Force recommends that a single national system for organ sharing be established; that its participants agree on and adopt uniform policies and standards by which all will abide; and that its governance include a broad range of viewpoints, interests, and expertise, including the public.

- The national network establish a method to systematically collect and analyze data related to both kidney and extrarenal organ procurement and transplantations. Further, to provide an ongoing evaluation of the scientific and clinical status of organ transplantation, a scientific registry of the recipients of kidney and extrarenal organ transplants should be developed and administered through the national network, and the Task Force urges the Congress to appropriate funds to initiate this activity.

Numerous other recommendations throughout the Task Force report made reference to the OPTN.

On September 30, 1986, the United Network for Organ Sharing (UNOS) was awarded a contract by the Health Resources and Services Administration (HRSA) of the Department of Health and Human Services (DHHS) to set up and operate the OPTN. UNOS is located in Richmond, Virginia. A separate scientific registry contract was awarded to UNOS to fulfill the data functions prescribed by the Task Force.

UNOS is a nonprofit, tax-exempt corporation established in March, 1984. UNOS is governed by a 32-member board of directors, 16 of whom are not physicians (see Table 19-1). The board has broad geographic representation, and includes transplant physicians and surgeons, organ procurement professionals, laboratory directors, transplant patients and family members as well as public members from the fields of ethics, religion, behavioral sciences, law, and health care financing.

The membership of UNOS includes qualified transplant centers, independent organ procurement organizations, tissue typing laboratories, voluntary health organizations and concerned members of the public. As of February 3, 1989, the 354 members included:

- 243 transplant centers.
- 51 independent organ procurement organizations.
- 39 tissue typing laboratories.
- 9 voluntary health organizations.
- 1 public member.
- 1 consortium.

Table 19-1

United Network for Organ Sharing
Board of Directors

Officers

President: H. Keith Johnson, M.D.
Dialysis Clinics, Inc.
1600 Hayes Street, Suite 300
Nashville, TN 37203
615-327-3061

Vice President: Robert J. Corry, M.D.
University of Iowa Hospitals and Clinics
Department of Surgery
Division of Transplantation
Iowa City, IA 52242
319-356-2545

Secretary: Robert Mendez, M.D.
St. Vincent's Medical Center
1893 Wilshire Boulevard
Los Angeles, CA 90057
213-483-6830

Treasurer: James S. Wolf, M.D.
Northwestern Memorial Hospital
Wesley Pavilion, Room 446
250 E. Superior Street
Chicago, IL 60611
312-908-7320

Past President: John C. McDonald, M.D.
LSU Medical Center
School of Medicine/Shreveport
P.O. Box 33932
1501 Kings Highway
Shreveport, LA 71130-3932
318-674-6100

Councillors

Region 1 Francis L. Delmonico, M.D.
Massachusetts General Hospital
Department of Surgery
32 Fruit Street
Boston, MA 02114
617-726-2825

Table 19-1 (continued)

Region 2	Clyde F. Barker, M.D. University of Pennsylvania School of Medicine Department of Surgery 3400 Spruce Street Philadelphia, PA 19104 215-662-2027
Region 3	William W. Pfaff, M.D. Department of Surgery University of Florida Box J-286, 1600 S.W. Archer Road Gainesville, FL 32610 904-392-3711
Region 4	Lynn H. Banowsky, M.D. 8042 Wurzbach, Suite 250 San Antonio, TX 78229 512-696-8081
Region 5	Thomas Berne, M.D. University of California School of Medicine 1200 N. State Street, Room 9900, Unit 1 Los Angeles, CA 90033 213-226-7720
Region 6	Douglas J. Norman, M.D. University of Oregon University Hospital Division of Nephrology 3181 S.W. Sam Jackson Park Rd. Portland, OR 97201 503-279-7880
Region 7	Alan G. Birtch, M.D. Southern Illinois University School of Medicine Division of Surgery, Transplantation P.O. Box 3926 800 N. Rutledge Springfield, IL 62708 217-782-8874
Region 8	Charles B. Anderson, M.D. Washington University School of Medicine Suite 5103 Queeny Barnes Hospital St. Louis, MO 63110 314-362-6490/7406

Table 19-1 (continued)

Region 9 Neil Lempert, M.D.
Albany Medical Center of Union University
Department of Surgery
Albany, NY 12208
518-445-5614

Region 10 J. Wesley Alexander, M.D.
University of Cincinnati Medical Center
Department of Surgery
231 Bethesda Avenue
Cincinnati, OH 45267-0558
513-558-6006

Heart Transplant Representation

R. Morton Bolman, III, M.D.
Washington University Medical Center
Division of Cardiothoracic Surgery
Barnes Hospital Plaza
Suite 3108
St. Louis, MO 63110
314-362-6190

Histocompatibility Representation

Wilma Bias, Ph.D.
Director, Tissue Typing Laboratory
Johns Hopkins University School of Medicine
807 Traylor Building
720 Rutland Avenue
Baltimore, MD 21205
301-955-3600

Nancy E. Goeken, Ph.D.
VA Medical Center - Iowa City
Room 10E-3, Tissue Typing Lab
Iowa City, IA 52240
319-338-0581

IOPA Representation

Rudolph C. Morgan
Organ Procurement Agency of Western NY, Inc.
1093 Delaware Avenue
Buffalo, NY 14209
716-883-0003

Table 19-1 (continued)

Ronald L. Dreffer
Ohio Valley Organ Procurement Center
231 Bethesda Avenue (ML 558)
Cincinnati, OH 45267
513-558-6867

Transplant Coordinator Representation

Anita L. Principe, B.S., M.P.A.
Montefiore Hospital
111 East 210th Street
Bronx, NY 10467
212-920-4459

Louise M. Jacobbi, A.A.S.
LSU Medical Center
Department of Surgery
P.O. Box 33932
1501 Kings Highway
Shreveport, LA 71130
318-674-6465

Voluntary Health Organization Representation

John Newmann, Ph.D.
Urban Institute
Health Policy Center
2100 M. Street, N.W.
Washington, D.C., 20037
202-857-8643

A. Bruce Bowden, Esq.
Buchanan Ingersoll Attorneys
57th Floor - 600 Grant Street
Pittsburgh, PA 15219
412-562-8919

Eric C. Sutton, Esq.
American Council on Transplantation
700 N. Fairfax St., Suite 505
Alexandria, VA 22314
703-836-4301

Richard A. Kahn, Ph.D.
American Diabetes Association, Inc.
National Service Center
1660 Duke Street
Alexandria, VA 22314
703-549-1500

Table 19-1 (continued)

General Public Representation

Charles E. Fiske
100 Bayberry Circle
Bridgewater, MA 02324
617-566-3430

James Childress, Ph.D.
Department of Religious Studies
Cocke Hall
University of Virginia
Charlottesville, VA 22903
804-924-6709

John A. Robertson, J.D.
University of Texas at Austin
727 East 26th Street
Austin, TX 78705
512-471-5151

Roger Evans, Ph.D.
Battelle Human Affairs Research Centers
4000 N.E. 41st Street
Seattle, WA 98105
206-525-3130 ext. 270

Rev. Robert S. Smith, Ph.L.
Director of Chaplaincy Services
University Hospital
State University of New York at Stony Brook
Stony Brook, NY 11794
516-444-2765

UNOS operates the Organ Center, the national clearinghouse at the operational center of the Organ Procurement and Transplantation Network. It gathers, analyzes, and publishes statistical information and carries out professional education programs in the field.

The original contract between UNOS and the Health Resources and Services Administration (HRSA) called for ten tasks to be completed by October 1, 1987 (McDonald, 1988:725). These tasks were as follows:

- (1) Develop a work plan.
- (2) Establish the National Organ Procurement and Transplant Network.
- (3) Develop and implement an information system plan.
- (4) Develop and maintain recipient registration system.
- (5) Match donors and recipients.
- (6) Develop a telephone communications system.
- (7) Develop transport assistance.
- (8) Develop procurement standards.
- (9) Develop high panel reactive antibody protocols.
- (10) Develop professional education.

Tasks 1, 4, and 6 through 10, while important, proved to be relatively noncontroversial. Tasks 2, 3, and 5 were found to be very controversial, and have only recently been resolved.

Two aspects of Task 2 were most difficult. The first was the recruitment of transplant centers into the OPTN. This proved to be a problem, as membership in UNOS was tied to compensation for transplantation. The other problem area was establishing membership criteria for all transplant centers, independent organ procurement agencies, and histocompatibility laboratories. This has been accomplished and promulgation

has been completed. Standards of membership focus on the credentials of the professionals involved, the environment in which they work, and ultimately the results of the transplants performed in each center. These standards focus on the quality of personnel and environment rather than numbers of grafts performed. They do not establish absolute survival numbers, since such criteria are commonly influenced by patient selection and might lead centers to avoid treating the most seriously ill patients. These criteria are fair and have been broadly acceptable. They in no way limit the number of centers that can be approved (McDonald, 1988:725).

The third task involved the creation of a detailed database that will provide and report essentially all transplant data in the United States. Through various data collection strategies, UNOS obtains data on what organs were removed from donors, where they were implanted, and includes the ability to track and ascertain what happened to all organs that were removed. Further data will be available concerning the results of all grafts and the causes of failure. On the one hand, this collection of data will require substantial reporting by transplant centers, a task that will in many instances be onerous; on the other hand, it will provide a database that is incomparable in the world of clinical medicine.

Task 5 represents an effort to assure that donors and recipients are appropriately matched and that the public will be convinced that those patients most in need will have the highest priority to receive an organ. There is also the necessity to establish that all recipients have equal access to available organs and are equitably treated. The approach that has been taken is to establish a system of priorities for which several factors can be used to determine which patients on a local list of waiting patients should

have the highest priority in receiving an available organ. The priority system includes the degree of match between the donor and the organ, the proximity of the organ to the patient, the length of time the patient has spent on the waiting list, the severity of the patient's illness, and degree of sensitization (see Rapaport, 1987:3118; Starzl et al., 1987:3073).

There is no doubt that the activities of UNOS are enormously significant. The creation of the National Organ Procurement and Transplantation Network represents a truly unique partnership between the government and the medical profession. To say the least, UNOS has proven to be a controversial organization, largely as a result of confusion as to the appropriate role and authority of UNOS. As differences are resolved, as they surely will be, it is likely that UNOS will live up to its expectations.

The United States Renal Data System (USRDS)

For years the renal community has criticized the federal government because of what it perceived as its lack of interest in creating a unified national database that could be used to conduct epidemiologic, clinical, economic, and public policy analyses of the delivery of end-stage renal disease services. While the Health Care Financing Administration has historically maintained considerable data resources, these were generally believed to be inadequate, inaccessible, and of questionable validity. The absence of a data system in the United States was often contrasted with the considerable data resources available in Europe. For years the European Dialysis and Transplant Association (EDTA) has maintained a comprehensive multinational database that has been the envy of nephrologists and transplant surgeons in the United States.

After many years of political lobbying by such notables as Dr. Christopher R. Blagg (Northwest Kidney Center) and Dr. Larry Hunsicker (University of Iowa), the United States Congress mandated the establishment of a "national end-stage renal disease registry." Details of the registry are contained in the Omnibus Reconciliation Act of 1986, Public Law 99-509 (section 9335), wherein the following is stated:

The Secretary shall establish a national end-stage renal disease registry the purpose of which shall be to assemble and analyze the data reported by network organizations, transplant centers, and other sources on all end stage renal disease patients in a manner that will permit --

- (A) the preparation of the annual report to the Congress required under subsection (g);
- (B) an identification of the economic impact, cost-effectiveness, and medical efficiency of alternative modalities of treatment;
- (C) an evaluation with respect to the most appropriate allocation of resources for the treatment and research into the cause of end-stage renal disease;
- (D) the determination of patient mortality and morbidity rates, and trends in such rates, and other indices of quality of care; and
- (E) such other analyses relating to the treatment and management of end stage renal disease as will assist the Congress in evaluating the end stage renal disease program under this section.

The Secretary shall provide for such coordination of data collection activities, and such consolidation of existing end stage renal disease data systems, as is necessary to achieve the purpose of such registry, shall determine the appropriate location of the registry, and shall provide for the appointment of a professional advisory group to assist the Secretary in the formulations of policies and procedures relevant to the management of such registry.

Clearly, as the foregoing implies, the proposed data system would take over functions previously within the purview of HCFA, as well as the ESRD Networks. The consolidation of data collection efforts as well as activities of various governmental agencies and government contractors would be primary activities associated with the new data system.

In May, 1988, the new national data system was created by contract (see USRDS Goldnotes, October 28, 1988). As described by the contractors, the new data system is intended to provide important information on the causes, diagnoses, and treatments of kidney failure. The USRDS will reportedly collect and analyze data on the incidence, prevalence, morbidity, and mortality of kidney failure in the United States.

The five-year, \$6.7 million project is funded by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDKD). The Health Care Financing Administration (HCFA) is working with NIDDKD on the project.

The system is operated by the USRDS Coordinating Center, run under a NIDDKD contract by the Urban Institute (a health, social, and economic policy research and education organization, located in Washington, D.C.) in conjunction with the University of Michigan at Ann Arbor. Dr. Philip Held is the Principal Investigator for the project, and Dr. Friedrich Port is the Co-Principal Investigator. The Coordinating Center is expected to have the data system fully operational within two years.

In order to meet its goals, the USRDS has sought input and support of the broad renal community. Thus, besides the Federal and contractor agencies involved, the USRDS organization includes several important advisory bodies: the Scientific Advisory Committee (see Table 19-2), the Data Forms Committee, the Data Management Advisory Committee, and the Renal Community Council.

Each of the foregoing groups is expected to contribute to the success of the USRDS by reviewing important renal program issues, helping to set research priorities, submitting ideas for research studies, and participating in

Table 19-2

United States Renal Data System (USRDS)
Scientific Advisory Committee (SAC) Members

Lawrence Agodoa, M.D. Director of Clinical Affairs Program NIH/NIDDK/DKUHD 5333 Westbard Avenue, Room 621 Bethesda, MD 20892 (301) 496-7571	NIDDK Clinical Affairs Program
Steven Alexander, M.D. Associate Professor Department of Pediatrics University of Texas S.W. Medical College 5323 Harry Hines Boulevard Dallas, TX 75235-9063 (204) 688-3438	Pediatrics
Christopher R. Blagg, M.D. Executive Director Northwest Kidney Center 700 Broadway Avenue Seattle, WA 98122 (206) 292-2941/2771	SAC Chair
Paul Eggers, Ph.D. Health Care Financing Administration 2504 Oak Meadows 6325 Security Boulevard Baltimore, MD 21207 (301) 966-6691	HCFA/Office of Research and Demonstrations
Roger W. Evans, Ph.D. Health and Population Study Center Battelle Human Affairs Research Centers 4000 N.E. 41st Street Seattle, WA 98105 (206) 525-3130	Quality of Life
Stacey C. FitzSimmons, Ph.D. Epidemiology Program Director NIH/NIDDK/DKUHD 5333 Westbard Avenue, Room 621 Bethesda, MD 20892 (301) 496-7571	NIDDK/Epidemiology Program

Table 19-2 (continued)

Philip J. Held, Ph.D. Center Director USRDS 2100 M Street, N.W., Suite 500 Washington, D.C. 20037 (202) 857-8668	Principal Investigator Coordinating Center
Lawrence G. Hunsicker, M.D. Department of Internal Medicine E300F General Hospital University of Iowa Hospital & Clinics Iowa City, Iowa 52242 (319) 356-4763	Transplantation Physician
Barry D. Kahan, M.D., Ph.D. Director, Division of Immunology and Organ Transplantation University of Texas Medical School at Houston 6431 Sannin Houston, TX 77030 (713) 792-5670	Transplantation Surgeon
Robert Luke, M.D. Director of Internal Medicine University of Cincinnati College of Medicine 231 Bethesda Avenue M.P.L. 557 Cincinnati, OH 45267 (513) 872-4231	Hemodialysis
Karl Nolph, M.D. Department of Medicine and Nephrology University of Missouri Health Science Center MA 436 Columbia, MO 65212 (314) 882-7991	Peritoneal Dialysis
Friedrich K. Port, M.D. Deputy Center Director USRDS Michigan Kidney Registry 315 West Huron, Suite 340 Ann Arbor, MI 48103 (313) 763-7794 (MKR) (313) 761-7983 (VA Med. Ctr.) (313) 769-7100 (VAMC for Paging)	Co-Principal Investigator Coordinating Center

Table 19-2 (continued)

James Tonascia, Ph.D. Professor Department of Epidemiology & Biostatistics Johns Hopkins School of Public Health 3029 Hygiene Building 615 North Wolfe Street Baltimore, MD 21205 (301) 955-8197/3074	Biostatistics
Paul Whelton, M.D., M.Sc. Professor of Medicine Carnegie Room 284 Johns Hopkins Hospital 600 North Wolfe Street Baltimore, MD 21205 (301) 955-4688 or 4777	Epidemiology

the analysis of the consolidated data base. Further, they will serve as focal points for the renal community to gain access to the USRDS.

The Coordinating Center is incorporating data from a variety of sources into the data base. The most important of these is HCFA's Program Management and Medical Information System (PMMIS) that tracks specific demographic and treatment data on the more than 135,000 patients with ESRD covered by the Medicare program.

In addition, the USRDS contractors plan to go beyond the PMMIS by adding data from HCFAs billing and utilization files, and possibly from non-HCFA sources such as the Veterans Administration, Bureau of the Census, Health Resources and Services Administration, Centers for Disease Control, and other public and private data collection agencies.

Lastly, as needed, the USRDS plans to work with HCFA to collect new primary data through the 18 national ESRD Networks, funded by HCFA under separate contracts. Such primary data collection will be initiated in the second year of the project.

The USRDS is currently in the Planning Phase. By the end of this phase (January, 1989), the PMMIS data will be operational in the new system. Other current HCFA data are targeted for inclusion early in the Implementation Phase (January 1989 - April 1990). Non-HCFA data will be added, as needed, late in this phase and during the Operational Phase (May 1990 - April 1993).

The Institute of Medicine Medicare ESRD Study

In October, 1988, the Institute of Medicine (IOM) was awarded a grant by HCFA to plan a major study on end-stage renal disease. On January 10,

1989, a cooperative agreement was awarded to the IOM by HCFA as an extension of the planning grant. The study is being directed by Dr. Richard Rettig, a well-known authority on policies related to the treatment of ESRD in the United States. It should be noted that this study is being conducted under a mandate from the United States' Congress. The legislation specified that the Department of Health and Human Services invite the Institute of Medicine to submit an application to do the study.

The main purpose of the IOM study is to develop, within a committee of experts, an in-depth review of the ESRD Program, and to assess the future direction of the Program and evaluate whether policy changes are warranted. The project goals and study objectives are directed toward five specific issues described in Section 403 (d) of the Omnibus Budget Reconciliation Act of 1987 (P.L. 100-203). The five issues are as follows:

- (1) access to treatment by both individuals eligible for Medicare benefits and those not eligible for such benefits;
- (2) the quality of care provided to end-stage renal disease beneficiaries as measured by clinical indicators, functional status of patients and patient satisfaction;
- (3) the effect of reimbursement on quality of treatment;
- (4) major epidemiological and demographic changes in the end-stage renal disease population that may affect access to treatment, the quality of care, or the resource requirements of the program; and
- (5) the adequacy of existing data systems to monitor these matters on a continuing basis.

To fulfill these objectives, the IOM has appointed a committee of diverse experts (see Table 19-3). Under the guidance of the Committee the study will: (1) compile an ESRD data book, (2) project the size and composition of the ESRD patient population for the next 10 years, (3) describe the population with chronic renal failure who are not entitled to

Table 19-3

Institute of Medicine
Council on Health Care Technology
Medicare ESRD Study Committee

<p>Norman G. Levinsky, M.D. (Chairman) Professor and Chairman Department of Medicine Boston University School of Medicine 80 East Concord Street Boston, MA 02118 (617) 638-7250</p>	<p>Philip J. Held, Ph.D. Senior Economist The Urban Institute 2100 M. Street, N.W. Washington, D.C. 20037 (202) 857-8668</p>
<p>Carmella A. Bocchino, R.N., M.B.A. 26 Huff Street Wharton, NJ 07885 (201) 989-0118</p>	<p>Susan M. Jaskula, M.S.W. 124 E. Rose St. Louis, MO 63119 (314) 771-5014</p>
<p>Christine K. Cassel, M.D. Chief, Section of General Internal Medicine University of Chicago Medical Center Room M640, Box 12 5841 South Maryland Avenue Chicago, IL 60637 (312) 702-3045</p>	<p>J. Michael Lazarus, M.D. Associate Professor of Medicine Renal Division Department of Medicine Brigham and Women's Hospital 75 Francis Street Boston, MA 02115 (617) 732-6137</p>
<p>Roger W. Evans, Ph.D. Battelle Human Affairs Research Center 4000 N.E. 41st Street P.O. Box C-5395 Seattle, WA 98105 (206) 525-3130</p>	<p>John E. Lewy, M.D. Professor and Chairman Department of Pediatrics Tulane University School of Medicine 1430 Tulane Avenue New Orleans, LA 70112 (504) 588-5456</p>
<p>Ronald M. Ferguson, M.D. Professor and Acting Chairman Department of Surgery Ohio State University College of Medicine 1654 Upham Drive Columbus, OH 43210 (614) 293-8545</p>	<p>C. Richard Neu, Ph.D. Director, RAND-UCLA Health Financing Center The RAND Corporation 1700 Main Street Santa Monica, CA 90406 (213) 393-0411</p>
<p>Sheldon Greenfield, M.D. The Institute for the Advancement of Health and Medical Care New England Medical Center Hospitals 750 Washington Street Boston, MA 02111 (617) 350-8080</p>	

Table 19-3 (continued)

Marjorie J. Powers, Ph.D.
Professor and Head
Department of Medical and Surgical
Nursing
College of Nursing
University of Illinois, Chicago
845 South Damon
Chicago, IL 60612
(312) 996-7955

John H. Sadler, M.D.
Division of Nephrology
Department of Medicine
University of Maryland School
of Medicine
655 West Baltimore Street
Baltimore, MD 21201
(301) 328-5720

Paul K. Whelton, M.D.
School of Public Health
Johns Hopkins University
615 N. Wolfe Street, Room 5025
Baltimore, MD 21205
(301) 955-4688

Marsha Wolfson, M.D.
Chief, Nephrology Section 111-C
Veterans Administration Medical
Center
Portland, OR 97201
(503) 220-8262

Medicare coverage, (4) describe Medicare-entitled ESRD patients, the types of care they receive, and the limitations on access to alternative treatments, (5) develop a conceptual framework for the evaluation of the quality of ESRD care, (6) review the literature on the quality of care for ESRD patients, (7) define a quality strategy for the ESRD program, (8) review the history of the reimbursement policies and of the impact of reimbursement policy on the quality of care, (9) review previous reimbursement analyses, (10) review the impact of reimbursement policy on structural aspects of ESRD facilities, (11) review the impact of reimbursement policy on innovation in ESRD, (12) review the demographic and epidemiologic trends in the ESRD population, (13) evaluate the needs for future research on the medical and administrative management of the ESRD population, and (14) review the data systems currently available and those that would be needed to adequately support the effective and efficient management of the ESRD program. In accordance with the legislation, the Committee will pursue appropriate consultation with a number of individuals and other interested parties.

Principal activities contributing to the deliberations of the committee will include:

- One public hearing, to provide opportunities for key organizations and constituencies to put their views about the ESRD program before the committee.
- One workshop on quality of care as it pertains to the ESRD program. The workshop will draw upon expert resources beyond the committee as needed, including the IOM Quality study.
- Staff and commissioned papers, including for instance: concepts and definitions of quality of care as they apply to the ESRD program; quality assessment techniques and applications; patient satisfaction measures; reimbursement effects on treatment innovation; ESRD patients with primary diagnosis of diabetes and hypertension; the elderly ESRD patient; and black and other non-white patients.

Finally, the Committee will produce a comprehensive report that will be transmitted to the Secretary of Health and Human Services and to the Congress. The provisional outline of the final report is as follows:

- I. Introduction
 - A. The historical context
 - B. The Congressional charge
 - C. The Committee response
- II. Background
 - A. Kidney failure and its treatments
 - B. The ESRD patient population
 - C. The provider community
 - D. National expenditures for ESRD patients
 - E. Federal agency responsibility and activity
- III. The Patient Population
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Clearly, as is apparent from the preceding discussion, the scope of the IOM study is very broad, and surely constitutes the most significant program analysis undertaken since the first Rettig (1980) report. The final report from the Committee will undoubtedly have a major impact on the delivery of ESRD services in the United States.

Discussion

The foregoing activities make it obvious that the treatment of end-stage renal disease is not being ignored by those individuals responsible for public health research and policy development. The National Institutes of Health, the Health Care Financing Administration, and the Health Resources and Service Administration are all actively involved in various projects and initiatives intended to improve both the diagnosis and treatment of renal failure. Other activities are intended to facilitate the delivery of dialysis and transplantation services to ESRD patients. Clearly, considerable resources have been allocated to these various tasks and efforts. The ultimate goal is improvement, for patients, clinicians, and policymakers. This is particularly true in the areas of quality assessment and quality assurance as attention has focused on outcomes and therapeutic endpoints. As pointed out by Dr. John Sadler (University of Maryland, Baltimore), "... the goal of all quality assurance activities within the End-Stage Renal Disease Program should be for the self-improvement of nephrologists, transplant surgeons, and other personnel involved in the direct provision of patient care." Quality assurance should not be viewed as regulatory oversight of the medicare profession. If it should be considered as such, quality assurance will ultimately fail as the medical profession comes to respond to quality assurance activities with animosity.

Quality assurance may well be one of the last bastions of hope for the continued improvement of the End-State Renal Disease Program. Recognizing this, it is noteworthy that various professional groups such as the Renal Physician's Association (RPA) and the American Society of Transplant

Surgeons (ASTS) have taken up the quality assurance charge on their own behalf. For example, the RPA, under the direction of Dr. Louis H. Diamond, facilitated the establishment of a National Task Force to identify "clinical indicators for nephrology." A list of these indicators, as developed by the Task Force, is presented in Table 19-4. In addition, under the aegis of the United Network for Organ Sharing, efforts are being made to carefully monitor transplant programs in an attempt to identify those programs whose survival rates are unacceptably low (i.e. fall within the lowest five percent of all centers nationally). As centers are identified which fit the aforementioned criterion, a review will be conducted to identify the possible reasons that patient outcomes are so poor. Once again, the intent of the review will be self-improvement.

The current report, with its primary focus on patient outcomes, underscores the importance of quality assurance activities. This report, like others we have prepared, is intended to emphasize the patient perspective, their needs, and their struggle with renal failure. As ESRD treatment technology has evolved, we have become very adept at saving lives. Unfortunately, we have been slow to appreciate the implications lifesaving therapy has for the individuals involved. As we focus our attention on quality of life, quality of care, and quality assurance, we come to grips with the very essence of the lifesaving activities within which we are involved. We begin to ask ourselves the questions with a deeper meaning, in particular, how effective are we at doing what we intend to do?

Table 19-4

Clinical Indicators for Nephrology

-
1. Hospitalization - Frequency
 2. Hospitalization - Length of stay
 3. Mortality
 4. Clotted dialyzers
 5. Vascular access problems: clotting, infection, steal, decreased flow
 6. Employment status
 7. Dementia
 8. Dialysis withdrawal rate
 9. Modality change rate
 10. Infection of PD catheter
 11. PD catheter flow problems
 12. Psychiatric morbidity
 13. Patient satisfaction with the treatment setting
 14. Patient satisfied with life and as an index of quality life measures
 15. Intra-dialytic problems including fever, hypotension, cramps, headache, nausea and vomiting, arrhythmia, chest pain, weight loss or gain
 16. Measures of clearance
 17. Transfusion rate
 18. Bone disease
 19. Hemoglobin levels
 20. Dietary compliance
 21. Blood pressure control
 22. Control of high blood glucose
 23. Patient transferred to another unit
 24. No show rate for dialysis
 25. Reduced time on dialysis at request of patients
 26. Reuse complaints
 27. Reuse accidents
 28. Referral to a transplant list
 29. Actual transplant rate
 30. Transplant graft survival
 31. Renal function posttransplant
 32. Transplant complication rate
 33. Transplant survival rate
 34. Complications of procedures such as temporary vascular access
 35. Complications of renal biopsy
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CHAPTER 20

SUMMARY AND CONCLUSION

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CHAPTER 20 SUMMARY AND CONCLUSIONS

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Introduction

The United States has made a major commitment to the treatment of end-stage renal disease (ESRD). This commitment was initially exemplified by the nearly unqualified extension of Medicare benefits to persons with renal failure in 1973. Although the wisdom of this approach has at times been questioned, there has been no concerted attempt to radically alter what is generally referred to as the End-Stage Renal Disease Program. In terms of lives saved, and annual per patient treatment expenditures, the Program has been an unqualified success. This has not silenced some critics, however, who believe that too few lives are saved at too great a cost, given other health care needs. Not surprisingly, these critics would argue that preventive health care initiatives should be both emphasized and supported generously. While such arguments cannot be dismissed as invalid, it is apparent that preventive health care efforts represent a longer term solution to what is clearly an immediate problem. Although it is conceivable that ESRD patients could be categorically denied access to renal replacement therapy, in a health care system such as ours, this is an unlikely solution. Instead, emphasis has been, and will continue to be, placed on making the delivery of renal replacement therapy as cost-efficient as possible. In this regard, kidney transplantation will play a critically important role for, as observed by Eggers (1988:223), "... renal transplantation is causing a convergence of the best clinical and economic outcomes for patients with end-stage renal disease."

This report has described at great length the considerable benefits that derive from kidney transplantation. The study was prospective with periodic follow-up of all patients. Based on this study, as well as others we have conducted, including the National Kidney Dialysis and Kidney Transplantation

Study, there is little doubt that a successful kidney transplant is the optimal form of therapy for the patient with renal failure. Kidney transplantation is clearly cost-effective when compared with other long-term approaches to the treatment of ESRD. Actual treatment expenditures distributed over time are considerably less than those associated with any form of dialysis. Moreover, patient benefits in terms of level of functioning, health status, and many other quality of life parameters are all significantly better than those of patients on dialytic therapy. The problem, however, is that not every patient with renal failure is, or ever will be, a candidate for transplantation. Many dialysis patients are too old to be considered for transplant, even though the average age of patients transplanted is increasing as patient selection criteria are relaxed (see Table 20-1). Also, the number of transplant candidates in the younger age groups is declining. As shown in Table 20-1, the average age of recipients of cadaveric transplants has gone up by about five years in the last decade. Persons over age 50 accounted for 16.5 percent of cadaver transplant recipients in 1978 and 27.9 percent in 1988. Other patients, as a result of blood transfusions, previous pregnancies, or an earlier failed transplant, may be immunologically sensitized. The literature clearly indicates that the presence of anti-HLA antibodies is an adverse prognostic factor in both first and subsequent graft recipients (Keown, 1985:328; Ladowski *et al.*, 1985:1218; Keown and Stiller, 1988:145). Therefore, while every effort should be made to increase the availability of kidney transplantation by improving the supply of donor organs, and making certain that patient referrals from the dialysis patient population are appropriate, there will be a continued need for all forms of dialytic therapy. This would change only if the indications for renal replacement therapy are altered, taking into consideration economic

Table 20-1
Age Distribution of Cadaver Transplant Recipients
by Year: 1978-1988

Age	YEAR (%)										
	1978	1979	1980	1981	1982	1983	1984	1985	1986	1987	1988
< 18	7.9	8.9	7.5	6.9	6.6	6.2	5.7	58.8	5.0	5.0	4.7
18-19	3.0	3.1	2.7	2.7	2.0	2.4	2.3	1.9	1.7	1.8	1.3
20-24	10.2	10.2	9.6	10.3	8.8	7.9	7.8	7.8	6.7	5.6	5.3
25-29	12.2	12.0	13.3	11.8	11.9	11.9	10.9	10.1	10.3	9.6	8.2
30-34	13.3	14.1	13.9	15.6	15.7	15.5	14.9	13.2	14.1	12.1	12.5
35-39	13.6	12.9	12.8	13.4	13.7	15.2	15.0	15.2	14.2	14.3	14.5
40-44	12.5	11.7	12.6	12.7	13.1	12.4	12.6	13.1	12.7	13.8	13.0
45-49	10.8	11.7	11.8	10.4	11.5	10.7	10.8	12.0	11.8	11.8	12.6
50-54	9.1	8.5	9.1	8.8	9.6	9.2	9.6	9.5	10.1	10.4	10.2
55-59	5.4	4.9	5.0	5.1	5.1	6.1	6.5	6.7	7.7	8.4	8.8
60-64	1.7	1.8	1.2	1.8	2.0	2.0	3.3	3.7	4.1	4.8	5.7
65+	0.3	0.2	0.6	0.4	0.2	0.7	0.7	1.1	1.6	2.3	3.2
Mean Age	36.3	35.8	36.3	36.3	37.0	37.3	38.1	38.7	39.6	40.5	41.5

Source: Paul Eggers, Ph.D., Office of Research, Health Care Financing Administration, Baltimore, Maryland

factors, with the intent of limiting or eliminating the need for dialysis, as is the case in the United Kingdom (Wing, 1983:1157).

Assuming that no sweeping changes are likely to occur in patient eligibility for renal replacement therapy, and that the supply of kidney donors will remain inadequate to meet the need for them, it is clear that dialysis will remain an important treatment modality for many ESRD patients. It is also noteworthy that there are new developments that may actually improve the longer-term prognosis of dialysis patients. Both recombinant human erythropoietin (r-HuEPO) and high flux dialysis are primary examples of technologies with great significance (Eschbach et al., 1987:73; Erslev, 1987:101). For example, r-HuEPO greatly enhances the quality of life of hemodialysis patients -- their energy level improves, strength and stamina increase, and various symptoms of anemia are relieved (Eschbach et al., submitted). Unfortunately, the annual maintenance costs associated with r-HuEPO has raised difficult questions related to Medicare coverage (Paganini, 1988:37; Bankhead, 1988:48).

In summary, it remains an error to consider dialysis and transplantation competitive ESRD treatment modalities. They must be viewed as complementary until one therapy is appropriately indicated for all patients and offers the most acceptable clinical and quality of life outcomes at the least cost for all patients. Moreover, it is also desirable if access to the optimal therapy is not limited because of availability. In other words, in the case of transplantation, the supply of donor organs should be sufficient to meet the need for them, otherwise an alternative form of therapy must be available to patients with renal failure.

Summary of Major Findings

In a report as substantial and comprehensive as this, it is difficult to agree on what constitute the major findings. Major, of course, is a relative concept. What one person considers major, another might consider trivial. Moreover, one's personal perspective and scientific interests will certainly be factors in interpreting the total "gestalt" of research findings presented here.

In the following review of our study findings, we will proceed chronologically chapter-by-chapter. We will exclude from discussion the study methodology, as this does not constitute a major research finding. One could, of course, use our discussion of the study methodology to criticize the generalizability of our findings or, possibly, the interpretation of our results. While in scientific discourse it is often popular to attack research findings based on a study's methodology, we feel our conclusions are valid, and have been, and will continue to be, supported by the research of others (e.g. Simmons et al., 1985:1577; 1987; 1988:379; 1988:415; 1988:481). To the extent that this is true, we do not believe that attacks on the grounds that our research cannot be generalized will survive the test of time.

As described in Chapter 3 of the report, major developments have occurred in clinical immunosuppression. Cyclosporine clearly represents the most significant development of the past decade. Our findings with respect to clinical immunosuppression are as follows:

- Cyclosporine markedly improved patient graft survival rates, had little effect on patient survival rates, but did reduce morbidity rates among transplant recipients generally.
- Because of methodological variations in trials involving the use of cyclosporine, it is difficult to state precisely the magnitude of effect cyclosporine has had on graft survival rates. Although some centers report one-year graft survival rates in excess of 90 percent, the national average would appear to be around 80 percent and improving.

- There are side-effects and complications associated with all immunosuppressive drugs, including cyclosporine. Many of these are dose-related and can be minimized through the use of multiple-drug approaches to immunosuppression.
- Nephrotoxicity is the most significant side-effect of cyclosporine, and is easily reversed through a reduction in cyclosporine dose, often accompanied by the addition of other immunosuppressive agents to the patient's maintenance protocol.
- Immunosuppressive protocols have become increasingly varied, and are best understood if their administration is divided into several phases: (1) induction treatment, (2) maintenance treatment, (3) chronic renal dysfunction treatment, and (4) anti-rejection treatment.
- Multiple drug immunosuppressive protocols can be distinguished as follows: (1) double-drug induction, (2) triple-drug induction, (3) quadruple-drug induction, (4) double-drug maintenance, (5) triple-drug maintenance, and (6) conversion protocols. Drugs can be administered sequentially or simultaneously.
- Cyclosporine conversion drug protocols, although attempted in the United States, have remained unpopular because of unsatisfactory outcomes. Moreover, as financial concerns have been alleviated, there has been less emphasis on converting cyclosporine patients to conventional immunosuppressive therapy.
- The most popular immunosuppressive protocols in use today in the United States are as follows:

	<u>Induction</u>	<u>Maintenance</u>
Double-Drug	CSA + PRED	CSA + PRED
Triple-Drug	AZA + PRED + ALG	AZA + PRED + CSA
Quadruple-Drug	AZA + PRED + ALG + CSA	AZA + PRED + CSA

Published reports indicate that there are major differences in patient outcomes based on immunosuppressive protocol. Our research findings support this observation.

- Given current practices within the renal transplant community, it does not seem prudent to pursue complete conversion from cyclosporine as a routine policy. Instead, only among patients who have developed complications associated with cyclosporine therapy, may conversion represent the most reasonable alternative available.

Based on our analyses, it is apparent that many changes have occurred in transplant immunology, most of which have been concurrent with the availability of cyclosporine. Consequently, well-controlled clinical trials are

an exception to the rule. Most frequently, small-scale observational studies have served as the basis for new developments in this rapidly evolving field involving a curious blend of basic science and clinical practice.

The patients included in our study were associated with five major renal transplant centers in the United States. These centers are as follows:

(1) the University of California, San Francisco, (2) the Ohio State University, (3) the University of Pittsburgh, (4) the University of Texas, Houston, and (5) the University of Wisconsin, Madison. Our descriptive analysis of the 396 patients in the study revealed the following:

- On various demographic and diagnostic variables, the patients in this study are similar to all patients transplanted in 1986 in the United States.
- For purposes of analysis, patients were divided according to their initial induction immunosuppressive protocol and primary disease diagnosis. There were no major differences among patients in terms of social and demographic characteristics. In short, patient case-mix is not a significant consideration in the analysis of differences in patient outcomes.

Chapter 5 is a detailed analysis of the transplant procedure and the administration of immunosuppressive drugs. Some of the more significant findings are as follows:

- The overall mean revascularization time was 25.3 minutes (S.D. = 14.4), with significant differences according to induction immunosuppressive protocol.
- Of the 396 patients who were included in the study, 14 patients (3.5%) experienced a graft failure and returned to dialysis during their initial hospital stay.
- Over 78 percent of all patients in the study did not require dialysis following transplantation.
- The average length of hospital stay in the study was 21.9 days (S.D. = 15.8) with a minimum of 6 days and a maximum of 252 days. Patients on double-drug induction therapy were discharged earlier than patients on triple-drug therapy.

- 97 percent of all patients began cyclosporine therapy at some time during their initial hospital stay.
- Drug dosages varied considerably based on induction protocol during the patient's initial hospital stay.
- From the time of initial hospital discharge, through the first year posttransplant, nearly all patients had their daily dosage of cyclosporine reduced considerably. The dosage (mg/kg/d) according to protocol at discharge, 3 months, 6 months, and 12 months is as follows:

<u>Induction Protocol</u>	<u>Cyclosporine Dosage</u>			
	<u>Discharge</u>	<u>3 months</u>	<u>6 months</u>	<u>12 months</u>
CSA + PRED	14.1	12.2	6.8	4.9
AZA + PRED + ALG	8.9	7.7	4.6	3.5

Based on our analysis, it is apparent that much is to be learned by actually following patients over time while monitoring their use of immunosuppressive drugs. Published reports clearly indicate that maintenance cyclosporine dosages are higher than they turn out to be in actual practice.

As discussed earlier, graft survival rates have improved considerably since the introduction of cyclosporine. What is most noteworthy, based on our analysis, is that graft survival rates vary according to initial induction immunosuppressive protocol. Our findings are as follows:

- The one-year graft survival rate of all eligible transplant recipients was 82.4 percent.
- Of those patients who initially received AZA + PRED + ALG, 89.2 percent still had functioning grafts at one year. The one year graft survival rates of patients who received CSA + PRED was 71.6 percent.
- Most graft failures occur within the first six months posttransplant.
- The one-year patient survival rate of all patients was 95.2 percent.
- The one-year patient survival rate for the AZA + PRED + ALG patient group was 95.2 percent, and for the CSA + PRED group the one-year patient survival rate was 89.9 percent.
- Most patient deaths occurred within 6 months posttransplant.

- In a multivariate analysis using the Cox proportional hazards model, we found that neither patient characteristics nor donor characteristics had a significant effect upon graft survival in the first 180 days following transplant surgery. The only variable that we were able to identify as a factor influencing graft survival was initial immunosuppressive protocol. Patients who initially received CSA + PRED had significantly lower graft survival rates in the first six months posttransplant compared with patients who initially received AZA + PRED + ALG.
- As was true of graft survival, the only significant variable influencing patient survival was initial immunosuppressive protocol, although protocol had a much less significant impact on patient survival than graft survival.

Our analysis leads us to conclude that both patient and graft survival rates vary according to the type of cyclosporine protocol upon which a patient is placed. Previous analyses have emphasized the role of cyclosporine, but have not always delineated the nature of differences among protocols.

Unfortunately, many published reports on the outcomes of kidney transplant recipients often fail to focus on important aspects of the posttransplant clinical course of patients. In Chapter 7 we examined several outcomes according to initial immunosuppressive protocol--renal function, adverse reactions to cyclosporine, disease symptomatology, and other posttransplant complications, as well as hospitalizations and disability days.

Among the more significant findings are the following:

- Patients who initially received AZA + PRED + ALG had better renal function following transplantation than did patients who initially received CSA + PRED. Differences persisted for up to 15 months posttransplant.
- CSA + PRED patients experienced more episodes of renal dysfunction than did patients who received AZA + PRED + ALG.
- The renal function of all patients improved with increasing time since transplantation.
- Neither the number of episodes of renal dysfunction nor serum creatinine levels differed by primary renal diagnosis.

- The two most commonly reported side effects associated with cyclosporine in this study were tremors and hypertension. Diabetic and nondiabetic patients were equally likely to experience adverse reactions to cyclosporine.
- Patients who initially received CSA + PRED experienced more adverse reactions to cyclosporine compared with patients who initially received AZA + PRED + ALG.
- With the exception of hypertension, the negative side effects of cyclosporine therapy decreased with increasing time since transplantation.
- The patients in this study reported that they frequently experienced a large number of symptoms and health related problems prior to transplant.
- With the exception of problems known to be associated with immunosuppressive therapy, patients reported fewer symptoms and health-related problems following transplantation.
- Although diabetic patients were more likely than nondiabetic patients to say that they often experienced various symptoms and health-related problems prior to transplantation, the two groups did not differ in the frequency of symptoms and health-related problems following transplantation.
- Neither hospital utilization in the year prior to transplantation nor hospital utilization in the first 15 months posttransplant varied by initial immunosuppressive protocol.
- Diabetic patients were hospitalized more often than nondiabetic patients in the year prior to transplantation and, in the months following transplantation, diabetic patients continued to be hospitalized more often than nondiabetic patients.
- Hospital utilization for all patient groups decreased with increasing time since transplantation.

As these results suggest, clinically valuable information can be gained by routinely following patients in both the early and late posttransplant period.

The rehabilitation of transplant recipients has become a major focus of attention. As graft and patient survival rates have improved, concern has shifted to those aspects of the patients' life that have been previously neglected. There is a general feeling that transplant recipients are

inadequately rehabilitated, given their rehabilitation potential. In this regard, the results of our analyses are noteworthy.

- We did not observe a dramatic improvement in the patients' ability to work, even though the average age of patients in this study was 42.2 years.
- The percentage of patients who said that they were able to work for pay on a full-time basis rose from 36.9 percent at three months posttransplant to 47.1 percent at 15 months posttransplant.
- Approximately one-half of the patients in this study reported that they were employed full-time or part-time during the year prior to surgery. At three months posttransplant, 28.7 percent of the patients were employed. Even at 15 months posttransplant, the percentage of patients employed was well below that of patients who were employed during the year prior to transplantation.
- Employment status did not differ significantly according to initial immunosuppressive protocol.
- Differences in employment status by primary renal diagnosis were much more apparent. Among nondiabetic patients, for example, 40.8 percent said they were able to work for pay full-time, three months following transplant. However, only 26.2 percent of diabetic patients said that they were able to work full-time.
- Nearly two-thirds of the diabetic patients indicated that they were unable to work at all, compared with 40 percent of nondiabetic patients.
- In general, the patients who were employed following their transplant surgery were also employed in the year prior to transplantation. Patients who considered themselves retired or homemakers remained as such posttransplant.
- Over 60 percent of the patients in this study were receiving some form of income support. Social Security Retirement or Disability Benefits and Supplement Security Income were the two most commonly cited sources of this support.
- Approximately two-thirds of the patients in this study had private insurance to help pay for their immunosuppressive drugs while approximately 20 percent of the patients received Medicaid benefits.
- For most patients in the study, finances were a major source of concern at the time of the transplant, and throughout the period posttransplant.

- Less than one-quarter of the patients reported that they had difficulty paying for their immunosuppressive drugs. Over 97 percent said that they received assistance in paying for their drugs. For two-thirds of the patients, this assistance was provided by private insurers.

As our analyses indicate, the rehabilitation of renal transplant recipients must be accorded priority status as a problem to be addressed.

Unfortunately, transplant recipients appear to exhibit a behavior pattern that is similar to that of people who have experienced a major cardiovascular event, such as a myocardial infarction or a coronary artery bypass procedure--they often fail to return to work and become the recipients of income support payments.

The rehabilitation potential of transplant recipients can be grossly impaired if patients have significant functional limitations. The results of our analysis are, therefore, quite surprising. They are as follows:

- There is a dramatic improvement in the level of physical functioning of transplant recipients following transplant surgery when compared with physical functioning one year prior to transplantation. This improvement persists over the 12 months posttransplant.
- Diabetic patients are more functionally impaired than nondiabetic patients, however, diabetics also had considerably higher levels of functional impairment prior to transplantation.
- Among nondiabetic patients, much of the improvement in physical functioning occurs in the first three months posttransplant, whereas among diabetic patients, the improvement is not apparent until 9-12 months posttransplant.
- No major differences in functional impairment were observed among patients based on their initial immunosuppressive protocol.
- Following transplant surgery, most transplant recipients engage in light and medium activities. Nondiabetic patients are more active than diabetic patients.
- Nearly all transplant recipients experience increasing vision problems posttransplant, most likely due to the maintenance administration of steroids.

Clearly, with respect to functional ability, the outlook for kidney transplant recipients, diabetic as well as nondiabetic, is very promising. There is little evidence that the physical limitations patients experience would substantially impair their ability to return to work, unless, of course, their previous line of work was excessively demanding.

As an issue apart from quality of life and vocational rehabilitation, the health status of transplant recipients has been the subject of few explicit studies. Our own research has been foremost in this area. In the present study, two standardized measures of health status were utilized. They are: the Sickness Impact Profile (SIP) and the Nottingham Health Profile (NHP).

The more significant of our research findings are the following:

- In general, kidney transplant recipients appear to present a fairly realistic picture of their health status. Overall, only about 12 percent of the patients expressed some level of negative satisfaction with their health.
- The perceived health status of diabetic patients is lower than that of nondiabetic patients.
- On the SIP and the NHP, the differences in the health status of diabetics and nondiabetics is most apparent in the dimensions reflecting physical functioning, rather than on the psychological dimensions.
- Neither perceived health status, nor health status as measured on the SIP or the NHP, differed greatly by immunosuppressive protocol.
- The perceived health status of both diabetic and nondiabetic patients improves over time, however, diabetic patients consistently report a lower perceived health status than nondiabetic patients. Scores on both the SIP and the NHP also improve over time for both patient groups.
- Improvement in the health status of patients during the period from 3-12 months posttransplant was much greater in the case of diabetic patients than it was for nondiabetic patients.

As the foregoing indicates, there is much similarity in the results of this

study as they pertain to functional ability and health status. We will now turn our attention to quality of life.

Historically we have distinguished between what we refer to as objective quality of life indicators, and those that are of a subjective nature. In Chapter 11 of this report we analyzed at great length a wide range of subjective quality of life indicators. The results were similar to those of our previous studies. Among the more salient findings are the following:

- Despite certain limitations in physical functioning and reduced labor force participation, transplant recipients are generally quite satisfied with their lives following transplant surgery.
- Overall, patients feel that they have adjusted well to their transplants.
- The vast majority of kidney transplant recipients report that they are happier following transplantation than they were prior to their transplant.
- Patients generally view themselves as either very independent or pretty independent in managing their lives.
- The overwhelming majority of transplant recipients have never felt that their transplant was a mistake.
- There is surprisingly little variation in subjective quality of life (e.g. life satisfaction, well-being, and psychological affect) over time, results consistent with our previous studies.
- Initial immunosuppressive protocol does not influence the subjective quality of life assessments of transplant recipients.
- Diabetic patients report a lower subjective quality of life than do nondiabetic patients. In general, diabetic patients are less satisfied with the quality of their lives, and are more likely to feel tied down than are nondiabetic patients.
- Diabetic patients are more dependent than nondiabetic patients.
- By 15 months posttransplant, patients in this study report higher levels of happiness than patients in the general population.
- A much higher percentage of nondiabetic patients say that they are very happy than is true for the general population. In contrast, a higher percentage of diabetic patients report that they are not too happy compared with the general population.

Clearly, as these results indicate, there is much less change in the subjective quality of life outcomes than in the objective quality of life outcomes of kidney transplant recipients. Moreover, the results of this study are similar to those of other studies that have looked at subjective quality of life longitudinally.

Another significant focus of this study was the costs (charges) associated with kidney transplantation. When successful, a kidney transplant is cost-effective, however, a failed graft experience can be very expensive. Moreover, a patient death is both a tragedy and expensive. Among the more important findings of Chapter 12 are the following:

- Transplant procedure charges ranged from a minimum of \$18,484 to a maximum of \$727,392. The mean transplant procedure charge was \$41,046.
- Of the 396 transplant procedures studied, the length of stay ranged from 6 to 252 days.
- Total transplant procedure charges at those centers that initially administered AZA + PRED + ALG averaged approximately \$10,000 less than those of centers that initially administered CSA + PRED (\$37,473 versus \$47,680).
- Moreover, during the first year following transplantation, the per patient hospital charges (excluding professional fees) for the CSA + PRED patient group (\$23,744) were over twice the per patient hospital charges for the AZA + PRED + ALG group (\$10,263).
- There was little difference in average transplant procedure charges for diabetic and nondiabetic patients (\$41,587 versus \$39,718). The cost of subsequent hospitalizations in the first three months following transplantation did not differ between diabetic and nondiabetic patients.
- During the period between 3 months and 12 months posttransplant, diabetic patients were hospitalized more often than were nondiabetic patients.
- Per patient hospital charges (excluding professional fees) during the first year following transplantation averaged \$22,098 for diabetic patients, compared with an average of only \$12,533 for nondiabetic patients.

- The 378 patients who were discharged from the hospital with functioning grafts were hospitalized an average of 20.5 days and transplant procedure charges for this group averaged \$37,522. In contrast, 14 patients experienced a graft failure and 4 patients died during their initial stay. These 18 patients were hospitalized, on average, 50.9 days and their hospital charges averaged \$115,949. Even with one extreme outlier omitted, the average transplant procedure charge for this group of patients was approximately \$80,000.
- High costs were found to be associated with graft failure. Twenty-four patients experienced a graft failure or died during the period between initial hospital discharge and three months posttransplant. For these 24 patients, hospital charges (excluding professional fees) during this follow-up period averaged \$31,049 per patient. Of the 346 patients whose grafts were still functioning three months posttransplant, hospital charges during this same period averaged \$3,835 per patient.
- Overall, transplant procedure charges for a "successful" kidney transplant patient averaged approximately \$37,500, with follow-up hospital charges during the first year posttransplant averaging an additional \$10,000.

Unfortunately, time and resources did not permit us to directly link our hospital charge data with Medicare reimbursement data for patients in this study. This, of course, would have permitted a more complete treatment of the costs versus charges issue that has been a major concern of health care policymakers.

The cost of immunosuppression was a major concern of the National Task Force on Organ Transplantation. Shortly following FDA approval of cyclosporine, it was determined that many patients were unable to have access to the drug because of their inability to pay. Subsequently, legislation was passed to remedy the immediate problems of Medicare-eligible transplant recipients. Chapter 13 examined the relationship between the Medicare Catastrophic Coverage Act and outpatient immunosuppressive drugs. Some of the key findings are as follows:

- Three different estimates were developed regarding the number of kidney transplants that are likely to be performed during the period 1988-1995. These included a base case, a modest increase, and a substantial increase. These estimates are as follows:

<u>Year</u>	<u>Base Case</u>	<u>Modest Increase</u>	<u>Substantial Increase</u>
1988	8,986	9,934	10,436
1989	9,005	11,026	13,054
1990	9,024	12,259	15,873
1991	9,044	13,654	19,383
1992	9,064	15,230	23,756
1993	9,084	17,013	29,208
1994	9,104	19,029	36,009
1995	9,124	21,310	44,495

- Three separate estimates of the number of living transplant recipients were also derived. In 1990, the totals are as follows: 49,274 (base), 53,739 (modest), and 58,145 (substantial). By 1995 the comparable estimates are 63,910 (base), 94,888 (modest), and 144,653 (substantial).
- Separate estimates were derived of the number of patients who would be alive with functioning grafts according to immunosuppressive protocol for the years 1988-1995.
- Additional estimates were developed of the number of patients that would be alive and also Medicare-eligible according to immunosuppressive protocol.
- The estimated annual costs of immunosuppressive drugs according to various protocols were also developed. These were initially based on published reports, and then, later, the data from the current study were used for re-estimation purposes. The results of both analyses are summarized below.

<u>Protocol</u>	<u>First Year</u>			<u>Subsequent Years</u>
	<u>Inpatient</u>	<u>Outpatient</u>	<u>Total</u>	

(1) Analysis based on published data

Conventional (w/o ALG)	\$ 95	\$ 852	\$ 947	\$ 793
Conventional (w/ALG)	10,385	852	11,237	793
Double-drug	638	8,126	8,764	8,198
Triple-drug (w/ALG)	4,034	7,756	11,790	8,227
Triple drug (w/OKT-3)	5,206	5,802	11,008	5,570
Quadruple-drug	5,626	7,193	12,819	6,870

(2) Analysis based on this study

Double-drug	\$ 550	\$5,338	\$5,888	\$4,028
Triple-drug (w/ALG)	4,274	3,899	8,173	3,157

As the foregoing results indicate, there is considerable variation in annual per patient expenditures for immunosuppressive drugs based on the patient's immunosuppressive protocol.

During the course of the study, data were obtained on the characteristics of kidney donors. All donors were cadaveric. Some of the more interesting results of our analysis are as follows:

- Most organ donors are male (63.9%) and white (88.1%).
- Donors in this study ranged from 2 to 63 years of age, with the average donor being 29.6 years (S.D. = 13.6).
- There were significant differences in the characteristics of donors across the transplant programs studied.
- 79.3 percent of all donors in the study received vasopressors, 70.5 percent received diuretics, 62.4 percent received steroids, and 32.3 percent received antibiotics in the 24 hours prior to organ removal.
- Among the 296 transplant procedures performed in the study, cold time ranged from 0 to 51 hours, with almost one-half reporting a cold time of 0 hours. Total pulsatile perfusion time ranged from 0 to 61.25 hours, with 35.1 percent reporting a total pulsatile perfusion time of 0 hours.
- Based on available information, 63.6 percent of the kidney donors in this study were multiple organ donors. Of the 396 donors, 41.9 percent also donated corneas, 38.9 percent donated hearts, 17.7 percent donated livers, and 14.4 percent donated bone. Only 11.4 were pancreas donors. The number and types of organs donated varied by transplant center.

In the future, given greater emphasis on multiorgan procurement, it is likely that the majority of donors will be the source of multiple organs and tissues.

As pointed out throughout this report, there is a tremendous shortage in the supply of donor organs, given the demand for them. Chapter 15 presented some public opinion poll data concerning both the procurement and distribution of donor organs. Some of the more relevant findings are as follows:

- Over the past several years people have become increasingly aware of organ transplantation and the need for donor organs.
- More people have received information on organ donation than ever before, and about one out of four carries an organ donor card.
- Over 88 percent of the people of the United States are most concerned that donor organs are distributed fairly and equally.
- 81.4 percent of the people believe that medical need, not social or economic factors, should be the only criterion used to select transplant recipients.
- About half the population does not feel that citizenship should be a consideration in deciding who gets transplanted.
- Country of origin was found to be a relevant consideration in the distribution of donor organs. People from Iran were clearly most likely to be the subject of discrimination, and Canadians the least likely.
- Over 86 percent of the United States' population feels that if no suitable recipient can be identified in the United States, it is acceptable to ship an organ to a foreign country where another patient from that country may benefit from a transplant operation.

Because of the special relationship between organ donation and transplantation, public opinion concerning the procurement and distribution of donor organs must be carefully assessed. Should public policy be at odds with public opinion, it is possible that the public's willingness to donate will be diminished.

While ability to pay is not a primary consideration in kidney transplantation, it, nonetheless, is an issue for the recipients of extrarenal transplants. Chapter 16 contains a detailed analysis of health insurer coverage policies. Although lengthy, the chapter addresses a single question --should ability to pay be a condition for gaining access to transplantation?

The major findings of this chapter are as follows:

- Over 37.0 million people in the United States do not have health insurance.

- In addition, between 26.0 and 27.0 million people are underinsured, thus lacking coverage for organ transplants.
- The development of insurance coverage policy is a very complex process that requires comprehensive technology assessments intended to answer a diverse set of questions.
- Cost is now a consideration in the coverage determination process.
- Medicare currently offers coverage for nearly all kidney transplants, as well as some heart, liver, and bone marrow transplants. Only coverage of kidney transplants is offered as an entitlement program.
- Medicaid coverage policies for transplants have become increasingly liberal, although at least two states have revised their coverage policies to exclude selected transplants.
- The majority of private insurers offer coverage for kidney, heart, and liver transplants, although HMOs tend to be more conservative in their policies than other private insurers. This presumably reflects their preventive health care orientation.
- Insurers follow a variety of reimbursement methodologies when offering coverage for organ transplants.
- While ability to pay should not be a consideration in gaining access to transplantation, it is apparent that it is, and will continue to be, a decisive factor for some patients. This is at odds with the public opinion poll data presented previously.

There is little doubt that there will be much controversy in the years to come regarding access to transplantation based on ability to pay. There is no clearcut solution: the specific problem of transplantation is part of the more general problem of the uninsured.

Recently there has been considerable discussion regarding the merits of the general concept of "centers of excellence" or "designated centers" for purposes of providing various specialized medical and surgical services. The concept has been applied by private insurers to the delivery of transplant services. Chapter 17 is a detailed analysis of how proregulatory and procompetition forces view the concept. The major findings of Chapter 17 are as follows:

- Given concerns related to cost, quality, and outcome, both public and private insurers have begun to target reimbursement to designated providers.
- Private insurers have negotiated discounted reimbursement rates, while public insurers, such as Medicare, have adopted a prospective payment approach.
- Upon careful review, it is apparent that neither the proponents of competition nor regulation differ as to the value of designation if the intent is to provide cost-effective, quality medical care.
- The proregulation and procompetition forces differ on several issues related to designation, including regionalization, quality of care indicators, patient advocacy, public release of outcome data, access to services, the criteria used to designate providers, and the duplication of facilities.
- The designation of centers for specialized health care services represents a desirable approach intended to cost-effectively meet the needs of patients for quality health care, while at the same time allowing insurers to conduct their business in a prudent manner.

Despite the relatively optimistic views expressed here concerning the designation concept, it will likely remain controversial among those persons who are strong proponents of competition. Unfortunately, ideological predispositions may simply cloud rational thought.

Chapter 18 is a discussion of what is commonly referred to as the "ethics of transplantation." The primary topics included in the discussion were: (1) organ procurement, (2) patient selection, (3) cost and reimbursement, (4) quality of life, and (5) resource allocation. The more salient findings of Chapter 18 are as follows:

- Because of the serious shortage of donor organs, numerous efforts are being made to increase supply. Some of these efforts, such as the use of anencephalic donors, have major ethical implications.
- The selection of transplant recipients remains ethically complex. Fortunately, United Network for Organ Sharing procedures have done much to assure that all transplant candidates are treated fairly and equitably.

- Both the cost of transplantation and the availability of reimbursement have significant ethical features that require vigilant attention.
- The quality of life of transplant recipients can be quite variable. While many patients will do very well posttransplant, others will encounter significant complications. These complications may protract the quality of dying experience for selected patients.
- Transplantation consistently raises a variety of issues related to resource allocation and rationing. While organ transplantation is expensive, the costs are often comparable to those associated with the treatment of other catastrophic diseases.

Ethicists will continue to carefully watch developments in the field of transplantation. Most of the primary issues are not easily resolved, and many are nearly metaphysical. This means that controversy is unavoidable.

Finally, in Chapter 19 we focused on the need for kidney transplantation, the availability of donor organs and the need for an integrated approach to the management of patients with renal failure. We also presented a brief review of several recent activities that are intended to address various problems associated with transplantation and the provision of services to patients with end-stage renal disease. These include: (1) The United Network for Organ Sharing, (2) The United States Renal Data System, and (3) The Institute of Medicine Medicare ESRD Study.

This concludes our summary of the major findings of this study. The picture that emerges is quite clear--kidney transplantation represents the most cost-effective treatment available for end-stage renal disease. Unfortunately, the supply of donor kidneys remains inadequate to meet the need for them.

REFERENCES

REFERENCES

- Aaron JH, Schwartz WB.
The Painful Prescription: Rationing Hospital Care. Washington, D.C.:
The Brookings Institution, 1984.
- Aaronson NK, Beckman JH, Bernheim JL, Zittoun R, eds.
The Quality of Life of Cancer Patients. New York: Raven Press, 1987.
- Abele R, Novick AC, Barun WE, et al.
Long-term results of renal transplantation in recipients with a
functioning graft for two years. Transplantation 34:264, 1982.
- Abbud-Filho M, Ramalho HJ, Barberato JB, et al.
A prospective study of conversion from cyclosporine to azathioprine:
comparison of clinical and morphologic findings. Transplant Proc.
20(3)(Suppl 3):164-168, 1988.
- Ackermann JR, LeFor WM, Kahana L, et al.
Prophylactic use of OKT-3 in renal transplantation: part of a
prospective randomized trial. Transplant Proc. 20(Suppl. 1):242-244,
1988.
- Aday LA, Fleming GV, Anderson R.
Access to Medical Care in the U.S.: Who Has It, Who Doesn't.
Chicago: Pluribus Press for the University of Chicago, 1984.
- Adu D, Michael J, McMaster P.
Conversion from cyclosporine to azathioprine/prednisolone. The Lancet
1(8425):392, 1985.
- Agran PF, Wehrle PF.
Injury reduction by mandatory child passenger safety laws. Am. J.
Public Health 75:128-129, 1985.
- Alexander JW, First MR, Majewski JA, et al.
The late adverse effect of splenectomy on patient survival following
cadaver renal transplantation. Transplantation 37:467, 1984.
- Amemiya H, Suzuki S, Manabe H, et al.
15-deoxyspergualin as an immunosuppressive agent in dogs. Transplant
Proc. 20(1)(Suppl. 1):229-232, 1988.
- American Council on Transplantation.
The U. S. Public's Attitudes Toward Organ Transplants/Organ Donation.
Princeton, NJ: The Gallup Organization, Inc., January, 1985.

- American Society of Transplant Surgeons. Current results and expectations of renal transplantation. JAMA 246:1330-1331, 1981.
- Andersen KS, Fox DM.
Impact of routine inquiry laws on organ donation. Health Affairs 7(5):65-77, 1988.
- Anderson CB, Tyler JD, Sicard GA, et al.
Pre-treatment of renal allograft recipients with immunosuppression and donor-specific blood. Transfusion 38:664-668, 1984.
- Andrews FM.
Social indicators of perceived life quality. Social Indicators Research 1:279-299, 1974.
- Andrews FM, Withey SB.
Developing measures of perceived life quality: results from several national surveys. Social Indicators Research 1:1-26, 1974.
- Andrews FM, Withey SB.
Social Indicators of Well-Being: Americans' Perceptions of Life Quality.
New York: Plenum Press, 1976.
- Andrulis DP, Beers VS, Bentley JD, Gage LS.
The provision and financing of medical care for AIDS patients in U.S. public and private teaching hospitals. JAMA 258:1343-1346, 1987.
- Angell M.
Cost containment and the physician. JAMA 254:1203-1207, 1985.
- Anonymous.
Hospital mortality rates. The Lancet 1(8494):1376, 1986.
- Antman K, Schnipper LE, Frei E, III.
The crisis in clinical cancer research: third-party insurance and investigational therapy. N. Engl. J. Med. 319:46-48, 1988.
- Arno PS.
The economic impact of AIDS. JAMA 258:1376-1377, 1987.
- Aroesty J, Rettig R.
The Cost Effects of Improved Kidney Transplantation. Report No. R-3099-NIH/RC. Santa Monica, CA: The Rand Corporation, 1984.
- Ascher NM, Evans RW.
Designation of liver transplant centers in the United States. Transplant Proc. 19:2405, 1987.
- Australian Multicentre Trials Group.
Preliminary report of the Australian multicentre trial of cyclosporin A in transplantation. Transplant Proc. 18:1236-1241, 1986.

- Bach FH, Sachs DH.
Transplantation immunology. N. Engl. J. Med. 317:489-492, 1987.
- Bach JF.
Immunosuppression. In: Hamburger J, Crosnier J, Bach J-R, Kreis, H. (eds.) Renal Transplantation: Theory and Practice. 2nd edition. Baltimore, MD: Williams and Wilkins, 1981:89-145.
- Baily MA.
Economic issues in organ substitution policy. In: Mathieu D, ed., Organ Substitution Technology. Boulder, CO: Westview Press, 1988:198-210.
- Baker R, Gordon R, Huffer J, Miller GH.
Experimental renal transplantation. I. Effect of nitrogen, cortisone and splenectomy. Arch. Surg. 65:702, 1952.
- Bankhead CD.
EPO's cost stirs questions about rationing renal care. Medical World News December 12, 1988:48.
- Banowsky L, Jaffers G, Singleton R, Hayes J, Nicastro JJ.
Multiple organ donation: its impact on the recovery of cadaver kidneys. J. Urol. 135:1157-1158, 1986.
- Barber C, Rettig R.
Costs and benefits of cyclosporine therapy in renal transplantation. Am. J. Kidney Diseases 5:344-346, 1985.
- Barna AD.
The clinical use of antilymphocyte globulins. In: Thompson RA (ed.) Recent Advances in Clinical Immunology. Edinburgh: Churchill Livingstone, 1977.
- Barnes BA.
Future trends in organ procurement. Heart Transplant 2:88-93, 1983.
- Barry JM, Serra JR, Hefty TR, et al.
Low dose cyclosporine strategy for cadaver kidney transplantation. Transplant Proc. 18(2)(Suppl. 1):125-127, 1986.
- Barsky AJ.
The paradox of health. N. Engl. J. Med. 318:414-418, 1988.
- Bart KJ, Macon EJ, Humphries AL.
A response to the shortage of cadaveric kidneys for transplantation. Transplant Proc. 11:455-457, 1979.
- Bart KJ, Macon EJ, Humphries AL, Jr., Baldwin RJ, et al.
Increasing the supply of cadaveric kidneys for transplantation. Transplantation 31:383-387, 1981.

- Bart KJ, Macon EJ, Whittier FC, Baldwin RJ, Blount JH.
Cadaveric kidneys for transplantation. Transplantation 31:379-382, 1981.
- Baumgartner WA, Reitz BA, Oyer PE, Stinson EB, Shumway NE.
Cardiac homotransplantation. Curr. Probl. Surg. 16:2-61, 1979.
- Bay WH, Hebert LA.
The living donor in kidney transplantation. In Cerilli JG, ed., Organ Transplantation and Replacement. Philadelphia, PA: J.B. Lippincott, 1988:272-283.
- Bean JF Jr, Makowiecki MM, Yessian MR.
The End-Stage Renal Disease Program: A Service Delivery Assessment National Report. Boston: Office of the Inspector General, U.S. Department of Health and Human Services, June, 1980.
- Beatty PG, Dahlberg S, Mickelson EM, et al.
Probability of finding HLA-matched unrelated marrow donors. Transplantation 45:714, 1988.
- Belitsky P, MacDonald A, Cohen A, Givner M, Sketris I.
Efficacy of a low-dose two-drug regimen of oral cyclosporine and delayed alternate day prednisone for immunosuppression in cadaver kidney transplantation. Transplant Proc. 20(3)(Suppl. 3):78-81, 1988.
- Bell JD, Marshall GD, Shaw BA, et al.
Alterations in human thoracic duct lymphocytes during thoracic duct drainage. Transplant Proc. 15:677-680, 1983.
- Bell MJ, Martin LW, Gonzalez LL, et al.
Alternate day single dose prednisone therapy: a method of reducing steroid toxicity. J. Pediatr. Surg. 7:223, 1972.
- Belzer FO.
Technical complications after renal transplantation. Morris PJ, ed., Kidney Transplantation: Principles and Practice. New York: Academic Press, 1979:267-284.
- Belzer FO.
Immunosuppressive agents -- a personal historical perspective. Transplant Proc. 20(3)(Suppl. 3):3-7, 1988.
- Belzer, FO, Glass NR, Miller DT. Should the availability of live-donor transplantation be reappraised? Dial Transplant 13:26, 1984.
- Belzer FO, Miller DT, Sollinger H, Glass NR.
Renal Transplantation -- a view of the 1980's. Seminars in Nephrology, 2:99-110, 1983.
- Benjamini E, Leskowitz S.
Immunology: A Short Course. New York: Alan R. Liss, Inc., 1987.

- Bennett AH.
Urologic complications of renal transplantation. In Cerilli JG, ed., Organ Transplantation and Replacement. Philadelphia, PA: J.B. Lippincott, 1988:433-438.
- Berg KR, Nghiem DD, Corry RJ.
Effect of transfusion of donor on allograft survival. Trnasplantation 34:344-346, 1982.
- Bergner M, Bobbitt RA, Carter WB, Gilson BS.
The Sickness Impact Profile: validation of a health status measure. Medical Care 14:57-67, 1976.
- Bergner M, Bobbitt RA, Kressel S, Pollard WE, Gilson BS, Morris JR.
The Sickness Impact Profile: conceptual formulation and methodology for the development of a health status measure. Int. J. Health Serivces 6:393-415, 1976.
- Bergner M, Bobbitt RA, Carter WB, Gilson BS.
The Sickness Impact Profile: development and final revision of a health status measure. Medical Care 19:787-805, 1981.
- Bergner L, Bergner M, Hallstrom AP, Eisenberg M, Cobb LA.
Health status of survivors of out-of-hospital cardiac arrest six months later. Am. J. Public Health 74:508-510, 1984.
- Beveridge T.
Cyclosporin-A: an evaluation of clinical results. Transplant Proc. 15(1):433-437, 1983.
- Billingham RE, Krohn PL, Medawar PB.
Effects of cortisone on survival of skin homografts in rabbits. Br. Med. J. 1:1157, 1951.
- Binik VM, Devins GM.
Transplant failure does not compromise quality of life in end-stage renal disease. Int. J. Psychiatry 16:281-292, 1986.
- Birkeland SA.
Cancer in cadaver kidney transplant patients. Surgery 93:504, 1983.
- Birkeland SA.
Cancer in transplanted patients -- the Scandia transplant material. Transplant Proc. 15:1071-1078, 1983.
- Birtch AG.
Patient selection for renal transplantation. In: Cerilli JG, ed., Organ Transplantation and Replacement. Philadelphia, PA: J.B. Lippincott CO., 1988:262-271.

- Blendon RJ.
What should be done about the uninsured poor. JAMA 260:3176-3177, 1988.
- Blendon RJ, Altman DE.
Public attitudes about health care costs: a lesson in national schizophrenia. N. Engl. J. Med. 311:613-616, 1984.
- Blohme I, Brynger H.
Malignant disease in renal transplant patients. Transplantation 39:23-24, 1985.
- Blommers TJ, Schanbacher B, Corry RJ.
Transplant and dialysis: the cost/benefit question. Iowa Med. 74:15-17, 1984.
- Bloom DE, Carliner G.
The economic impact of AIDS in the United States. Science 239:604-610, 1988.
- Booth W.
A change of heart. Science 240:976, 1988.
- Borel JF.
The history of cyclosporin A and its significance. In: White DJG (ed.), Cyclosporine A. New York: Elsevier Press, 1982:5-17.
- Borel JF.
Cyclosporine: historical perspectives. Transplant Proc. 15 (Suppl. 1 and 2):2219-2229, 1983.
- Borel JF, Feurer C, Gubler HV, Stahelin H.
Biological effects of cyclosporin A: a new anti-lymphocytic agent. Agents Actions 6:468-475, 1976.
- Borel JF, Lafferty KJ.
Cyclosporine: Speculation about its mechanism of action. Transplant Proc. 15:1881-1885, 1983.
- Boudreax JP, McHugh L, Canafax DM, et al.
The impact of cyclosporine and combination immunosuppression on the incidence of posttransplant diabetes in renal allograft recipients. Transplantation 44:376-381, 1987.
- Boybjerg RR, Held PJ, Diamond LG.
Provider-patient relations and treatment choice in the era of fiscal incentives: the case of the End-Stage Renal Disease Program. The Milbank Quarterly 65:177-202, 1987.
- Bowen OR.
Shattuck Lecture -- what is quality care? N. Engl. J. Med. 316:1578-1580, 1987.

- Bradburn NM.
The Structure of Psychological Well-Being. Chicago: Aldine, 1969.
- Bradburn NM, Caplovitz D.
Reports on Happiness. Chicago: Aldine, 1965.
- Bradley BA, Gore SM, Gilks WR, et al.
Cyclosporin and graft survival. The Lancet 2 (8506):568-569, 1986.
- Bradley JW, McCabe JL, O'Connor KJ, Cho SF.
Multiorgan donors: A limited resource. Transplant Proc. 20(5):846, 1988.
- Brenner MK, Munro AJ.
The major histocompatibility system, antigen preservation, and graft rejection. Heart Transplantation 1:268-274, 1982.
- Brock DW.
Ethical issues in recipient selection for organ transplantation. In: Mathieu D., ed., Organ Substitution Technology. Boulder, CO: Westview Press, 1988:86-99.
- Brook RH, Avery AD, Greenfield S, Harris LJ, Lelah T, Solomon NE, Ware JE, Jr.
Quality of Medical Care Assessment Using Outcome Measures: An Overview of Method. Publication No. R-2021/1-HEW, Santa Monica, CA: The Rand Corporation, 1976.
- Brook RH, Lohr KN.
Monitoring quality of care in the Medicare program. JAMA 258:3138-3141, 1987.
- Broyer M, Gagnadoux MF, Guest G, Niaudet P.
Triple therapy including cyclosporin A versus conventional regimen -- a randomized prospective study in pediatric kidney transplantation. Transplant Proc. 19:3582-3585, 1987.
- Bulpitt CJ.
Randomized Controlled Clinical Trials. The Hague: Martinus Nijhoff, 1983.
- Bulpitt CJ.
Meta-analysis. The Lancet 2(8602):93-94, 1988.
- Bunker JP, Fowles J, Schaffarzick R.
Evaluation of medical-technology strategies: effects of coverage and reimbursement (first of two parts). N. Engl. J. Med. 306:620-624, 1982.
- Bunker JP, Luft HS, Enthoven A.
Should surgery be regionalized? Surg. Clin. North Am. 62(4):657-668, 1982.

- Bunker JP, Fowles J, Schaffarzick R.
Evaluation of medical-technology strategies: proposal for an Institute for Health Care Technology (second of two parts). N. Engl. J. Med. 306:687-692, 1982.
- Bunzendahl H, Wonigeit K, Klempnauer J, Broelsch C, Pichlmayr R.
Cyclosporine and steroids: effects on the clinical course after renal allotransplantation. Transplant Proc. 15(Suppl. 1 and 2):2531-2534, 1983.
- Burke GW, Simmons RL, Canafax DM, et al.
Initial experience with OKT-3 for prophylaxis and treatment of rejection in kidney, liver, and pancreas allografts. Transplant Proc. 20 (Suppl. 1):252-253, 1988.
- Burley JA, Stiller CR.
Emotionally-related donors and renal transplantation. Transplant Proc. 17(6 Suppl 3):123-127, 1985.
- Burlingham WJ, Grailer A, Sparks-Mackety EMF, Sondel PM, Sollinger HW.
Improved renal allograft survival following donor-specific transfusions. II. In vitro correlates of early (DST-type) rejection episodes. Transplantation 43:41-46, 1987.
- Burns CL.
Ophthalmologic aspects of dialysis and transplantation. In: Tilney NL, Lazarus JM, eds., Surgical Care of the Patient with Renal Failure. Philadelphia, PA: W.B. Saunders, 1982:170-183.
- Buxton MJ, Acheson R, Caine N, Gibson S, O'Brien BJ.
Costs and Benefits of the Heart Transplant Programmes at Harefield and Papworth Hospitals. DHHS Research Report No. 12, London, HMSO, 1985.
- Bye B, Schechter E.
A Technical Introduction to the 1978 Survey of Disability and Work. Baltimore, MD: Division of Disability Studies, Social Security Administration, 1979.
- Bye B, Schechter E.
1978 Survey of Disability and Work: Technical Introduction. SSA Publication No. 13-11745. Baltimore MD: Office of Research and Statistics, Office of Policy, Social Security Administration, 1982.
- Byrne G.
Cyclosporine turns five. Science 242:198, 1988.
- Calne RY.
The development of immunosuppressive therapy. Transplant Proc. 13(Suppl. 1):44-49, 1981.

Calne RY.

Twenty years' experience of immunosuppression in organ transplantation. Transplant Proc. 14:91-97, 1982.

Calne RY (ed.)

Transplantation Immunology: Clinical and Experimental. New York: Oxford University Press, 1985.

Calne RY.

Cyclosporin in cadaveric renal transplantation: 5-year follow-up of a multicentre trial. The Lancet 2 (8557):506-507, 1987.

Calne RY, Rolles K, White DJG, et al.

Cyclosporin A initially as the only immunosuppressant in 34 recipients of cadaveric organs; 32 kidneys, 2 pancreas, and 2 livers. The Lancet 2:1033, 1979.

Calne RY, White DJG, Evans DB, et al.

Cyclosporin A in cadaveric organ transplantation. Br. Med. J. 282:934, 1981.

Calne RY, White DJG, Evans DB, Wight C.

Three years' experience with cyclosporin A in clinical cadaveric kidney transplantation. In: White DJG (ed.), Cyclosporine A. New York: Elsevier Press, 1982:347-353.

Calne RY, Wood AJ.

Cyclosporine in cadaveric renal transplantation: 3-year follow-up of a European Multicentre Trial. The Lancet 2(8454):549, 1985.

Campbell A.

Subjective measures of well-being. American Psychologist, February, 1976:117-124.

Campbell A, Converse PE, Rodgers WL.

The Quality of American Life. New York: Russell Sage Foundation, 1976.

Campbell A, Converse PE.

The Quality of American Life, 1978. (ICPSR Study Number 7762) Ann Arbor, MI: Inter-University Consortium for Political and Social Research, 1980.

Canadian Multicentre Transplant Study Group.

A randomized clinical trial of cyclosporine in cadaveric renal transplantation. N. Engl. J. Med. 309:809-815, 1983.

Canadian Multicentre Transplant Study Group.

A randomized clinical trial of cyclosporine in cadaveric renal transplantation: analysis at three years. N. Engl. J. Med. 314:1219-1225, 1986.

- Canafax D, Sutherland D, Ascher NL, Simmons R, Najarian J.
Cyclosporine nephrotoxicity in renal allograft recipients: conversion to azathioprine to improve renal function. Transplant Proc. 15(Suppl. 1):2874, 1983.
- Canafax DM, Martel EJ, Ascher NL, et al.
Two methods of managing cyclosporine nephrotoxicity: conversion to azathioprine, prednisone, or cyclosporine, azathioprine, and prednisone. Transplant Proc. 17:1176-1177, 1985.
- Canafax DM, Savik SK, Draxler CA.
Cox regression analysis of outcome risk factors in 519 renal allograft recipients. Transplant Proc. 19:1947-1948, 1987.
- Canafax DM, Sutherland DER, Matas AJ, et al.
Cyclosporine and immunosuppressive regimens in renal transplantation. N. Engl. J. Med. 319:1287-1288, 1988.
- Caper P.
Defining quality in medical care. Health Affairs 7(1):49-61, 1988.
- Caper P.
Solving the health care dilemma. N. Engl. J. Med. 318:1535-1536, 1988.
- Caplan AL.
Ethical and policy issues in the procurement of cadaver organs for transplantation. N. Engl. J. Med. 311:981-983, 1984.
- Caplan AL.
Ethical issues raised by research involving xenografts. JAMA 254:3339-3343, 1985.
- Caplan AL.
Equity in the selection of recipients for cardiac transplants. Circulation 75:10-19, 1987.
- Caplan AL.
Ethical issues in the use of anencephalic infants as a source of organs and tissues for transplantation. Transplant Proc. 20(4)(Suppl 5):42-49, 1988.
- Caplan, AL.
Professional arrogance and public misunderstanding. Hastings Cent. Rpt. 18(2):34-37, 1988.
- Caralps A.
History of immunosuppression in kidney transplantation. Transplant Proc. 20(5)(Suppl 6):3-4, 1988.
- Caralps A, Lloweras S, Masramow J, et al.
Urinary calculi after renal transplantation. The Lancet 1:544, 1977.

- Carlson DM, Johnson WJ, Kjellstrand CM.
Functional status of patient with end-stage renal disease. Mayo Clin. Proc. 62:338-344, 1987.
- Carpenter C, Milford E, Kirkman R, Strom T, Lazarus J, Tilney N.
Stability of renal allograft recipients after conversion from cyclosporine to azathioprine. Transplant Proc. 17(Suppl. 1):261, 1985.
- Carpenter BJ, Tilney NL, Strom TB, et al.
Cyclosporin A in cadaver renal allografts. Kidney Int. 19:265, 1981.
- Carosella J.
Picking up the pieces: the unsuccessful kidney transplant. Health Soc. Work 9:142-152, 1984.
- Cecka JM.
The transfusion effect. In: Terasaki PI (ed.), Clinical Transplants. 1987. Los Angeles, CA: UCLA Tissue Typing Laboratory, 1987:287-301.
- Cerilli GJ, ed.
Organ Transplantation and Replacement. Philadelphia, PA: JB Lippincott, 1987.
- Cerilli GJ.
Highlights of recent progress in transplantation. In: Cerilli GJ (ed.), Organ Transplantation and Replacement. New York: J.B. Lippincott, Co., 1988:16-33.
- Chalmers TC.
Third party payers and investigational therapy. N. Engl. J. Med. 319:1228, 1988.
- Chapman JR, Griffiths D, Harding NGL, Morris PJ.
Reversibility of cyclosporine nephrotoxicity after three months' treatment. The Lancet 1(8421):128-130, 1985.
- Chapman J, Morris P.
Cyclosporine nephrotoxicity and the consequences of conversion to azathioprine. Transplant Proc. 17(Suppl. 1):254, 1985.
- Chapman JR, Marcen R, Arias M, Raine AEG, Dunnhill MD, and Morris PJ.
Hypertension after renal transplantation: a comparison of cyclosporine and conventional immunosuppression. Transplantation 43:860-864, 1987.
- Chetwynd J, Swainson C.
The cost of renal transplants. N.Z. Med. J. 100(822):247-248, 1987.
- Chorba TL, Reinfurt D, Hulka BS.
Efficacy of mandatory seat-belt use legislation. JAMA 260:3593-3597, 1988.

- Churchill DN, Torrance GW, Taylor DW, et al.
Measurement of quality of life in end-stage renal disease: the time tradeoff approach. Clin. Invest. Med. 10(1):14-20, 1987.
- Churchill LR.
Rationion Health Care in America: Perceptions and Principles of Justice. Notre Dame, Ind: University of Notre Dame, 1987.
- Coates A, Gebiski V, Bishop JF, et al.
Improving the quality of life during chemotherapy for advanced breast cancer. N. Engl. J. Med. 317:1490-1495, 1987.
- Cohen BD.
Hard Choices: Mixed Blessings of Modern Medical Technology. New York: Putnam's, 1986.
- Consensus Conference Report.
Liver transplantation. JAMA 250:2961-2964, 1983.
- Copeland JG, Stinson EB.
Human heart transplantation. Curr. Probl. Cardiol. 4:4-51, 1979.
- Cortesini R, Renna ME, Monari C, et al.
Total lymphoid irradiation in clinical transplantation. Experience in 30 high risk patients. Transplant Proc. 17:1291, 1985.
- Cosimi AB, Burton RC, Colvin RB, et al.
Treatment of acute renal allograft rejection with OKT-3 monoclonal antibody. Transplantation 32:535-539, 1981.
- Council on Scientific Affairs.
Oregon donor recruitment. JAMA 246:2157-2158, 1981.
- Council on Scientific Affairs.
Introduction to the management of immunosuppression. JAMA 257:1781-1785, 1987.
- Council of the Transplantation Society.
Commercialization in transplantation: the problems and some guidelines for practice. Transplantation 41:1-3, 1985.
- Crawshaw R, Garland MJ, Hines B, Lobitz C.
Oregon Health Decisions: an experiment with informed community consent. JAMA 254:3213-3216, 1985.
- Croog SH, Levine S, Testa MA, et al.
The effects of antihypertensive therapy on quality of life. N. Engl. J. Med. 314:1657-1664, 1986.

- Crosnier, J, Broyer M.
Treatment of chronic renal failure in children. In: Hamburger J, Crosnier J, Grunfeld JP, eds., Nephrology. New York: John Wiley and Sons, 1979:1361.
- Crosnier J.
Extrarenal complications. In: Hamburger J, Crosnier J, Bach JF, Kreis H, eds. Renal Transplantation: Theory and Practice. Second edition. Baltimore, MD: Williams and Wilkins, 1981:232-267.
- Culliton BJ. Politics of the heart. Science 241:283, 1988.
- Culyer AJ.
Assessing cost-effectiveness. In Banta HD, ed., Resources for Health: Technology Assessment for Policy Making. New York: Praeger, 1982:107-120.
- Daley J, Jencks S, Draper D et al.
Predicting hospital-associated mortality for Medicare patients. JAMA 260:3617-3624, 1988.
- Daniels N.
Why saying no to patients in the United States is so hard. N. Engl. J. Med. 314:1380-1383, 1986.
- Daniels N.
Why saying no to patients in the United States is so hard. N. Engl. J. Med. 315:1297, 1986.
- Debure A, Chkoff N, Chatenoud L, et al.
One-month prophylactic use of OKT-3 in cadaver kidney transplant recipients. Transplantation 45:546-553, 1988.
- Decker MD, Dewey MJ, Hutcheson RH, Jr., Schaffner W.
The use and efficacy of child restraint devices. JAMA 252:2571-2575, 1984.
- Decker MD, Graitcer PL, Schaffner W.
Reduction in motor vehicle fatalities associated with an increase in the minimum drinking age. JAMA 260:3604-3610, 1988.
- Deierhoi MH, Sollinger HW, Kalayoglu M, Belzer FO.
Quadruple therapy for renal transplantation. Transplant Proc. 19:1917-1919, 1987.
- Deierhoi MH, Sollinger HW, Kalayoglu M, Belzer FO.
Quadruple immunosuppression in 305 consecutive cadaver renal allografts. Clin. Transplantation 1:71-74, 1987.
- Delmonico FL, Auchincloss H, Yang H, Russell PS, Cosimi AB.
Indications and outcome of OKT-3 therapy after liver, pancreas, and renal transplantation. Transplant Proc. 20(Suppl. 1):249-251, 1988.

- Dempster WJ, Lennox B, Boag JW.
Prolongation of survival of skin homotransplants in rabbit by irradiation of host. Br. J. Exp. Pathol. 31:670, 1950.
- de Saitonge CM, Vere DW.
Current Problems in Clinical Trials. Oxford: Blackwell, 1984.
- Detsky AS, Sackett DL.
When was a 'negative' clinical trial big enough? How many patients you needed depends on what you found. Arch. Intern. Med. 145:709-712, 1985.
- De Vecchi A, Tarantino A, Montagnino G, et al.
A controlled prospective trial of triple therapy with low-dose azathioprine, cyclosporine, and methylprednisolone in renal transplantation. Transplant Proc. 19:1933-1934, 1987.
- Diethelm AG, Sterling WA, Hartley MW, Morgan JM.
Alternate-day prednisone therapy in recipients of renal allografts. Arch. Surg. 111:867, 1976.
- Donabedian A.
Evaluating the quality of medical care. Milbank Mem. Fund Q. 44:166-206, 1966.
- Donabedian A.
A Guide to Medical Care Administration, Vol. II: Medicare Care Appraisal. New York: American Public Health Association, 1969.
- Donabedian A.
The quality of medical care: methods for assessing and monitoring the quality of care for research and for quality assurance programs. Health, United States, 1978. DHEW Publication No. (PHS) 78-1232, Public Health Service. Washington D.C.: U.S. Government Printing Office, 1978.
- Donabedian A.
Explorations in Quality Assessment and Monitoring, Volume I. The Definition of Quality and Approaches to its Assessment. Ann Arbor, MI: Health Administration Press, 1980.
- Donabedian A.
Explorations in Quality Assessment and Monitoring, Volume II. The Criteria and Standards of Quality. Ann Arbor, MI: Health Administration Press, 1982.
- Donabedian A.
Volume, quality, and the regionalization of health care services. Med. Care 22:95-96, 1984.

- Donabedian A.
The Methods and Findings of Quality Assessment and Monitoring: An Illustrated Analysis. Ann Arbor, MI: Health Administration Press, 1985.
- Donabedian A.
 Quality assessment and assurance: unity of purpose, diversity of means. Inquiry 25:173-192, 1988.
- Donabedian A.
 The quality of care: how can it be assessed? JAMA 260:1743-1748, 1988.
- Doubilet P, Weinstein MC, McNeil BJ.
 Use and misuse of the term "cost-effective" in medicine. N Engl. J. Med. 314:253-256, 1986.
- Dubois RW, Brook RH, Rogers WH.
 Adjusted hospital death rates: a potential screen for quality of medical care. Am. J. Public Health 77:1162-1166, 1987.
- Dubois RW, Rogers WH, Moxley JH, Draper D, Brook RH.
 Hospital inpatient mortality: is it a predictor of quality? N. Engl. J. Med. 317:1674-1680, 1987.
- Dubois RW, Rogers WH, Draper D, Brook RH.
 Does hospital mortality predict quality? N. Engl. J. Med. 318:1624, 1988.
- Dummer JS, Hardy A, Poorsattar A, Ho M.
 Early infections in kidney, heart, and liver transplant recipients on cyclosporine. Transplantation 36:259-267, 1983.
- Editorial.
 Reaping the whirlwind. Hospitals 55:55-56, 1981.
- Editorial.
 Lymphoma in organ transplant recipients. The Lancet 1(8377):601-603, 1984.
- Editorial.
 Blood transfusion and allograft survival. The Lancet 1(8381):830-831, 1984.
- Editorial.
 Transplant osteonecrosis. The Lancet 1(8435):965-966, 1985.
- Editorial.
 Hospital mortality rates. The Lancet 1(8494):1376, 1986.
- Editorial.
 Health care inequity in the USA. The Lancet 2(8606):316-317, 1988.

Editorial.

When are cyclists going to wear helmets? The Lancet 1(8578):159-160, 1988.

Editorial.

Time to abandon pre-transplant blood transfusion? The Lancet 1(8585):567-568, 1988.

Eggers PW.

Trends in reimbursement for end-stage renal disease: 1974-1979. Health Care Financing Review 6(1):31-38, 1984.

Eggers PW.

Effect of transplantation on the Medicare end-stage renal disease program. N. Engl. J. Med. 318:223-229, 1988.

Eggers PW, Connerton R, McMullan M.

The Medicare experience with end-stage renal disease: trends in incidence, prevalence, and survival. Health Care Financing Review 5(3):69-88, 1984.

Eggers PW.

Prospective payment system and quality: early results and research strategy. Health Care Financing Review. Annual Supplement, 1987.

Elion GB, Bingi E, Hitchings GH.

Study on condensed pyrimidine systems. IX. The synthesis of some 6-substituted purine. J. Am. Chem. Soc. 74:411, 1952.

Elion GB, Callahan S, Bieber S, Hitchings GH, Rundles RW.

A summary of investigations with 2-amino-6-[methyl-4-nitro-5-imidazolylthio] purine (B.Z. 57-322). Cancer Chemother. Pharmacol. 12:85, 1961.

Ellwood PM.

Outcomes management: a technology of patient experience. N. Engl. J. Med. 318:1549-1556, 1988.

Emery RW, Cork RC, Levinson MM, et al.

The cardiac donor: a six-year experience. Ann. Thor. Surg. 41:356-362, 1986.

Engemann R, Gassel HJ, LaFrenz E, et al.

The use of 15-deoxyospergualin in orthotopic rat liver transplantation. Transplant Proc. 20(1)(Suppl.1):237-239, 1988.

Englehardt HT.

Shattuck Lecture: Allocating scarce medical resources and the availability of organ transplantation. N. Engl. J. Med. 311:66-71, 1984.

Enthoven AC.

Managed competition: an agenda for action. Health Affairs 7(3):25-47, 1988.

Erslev A.

Erythropoietin coming of age. N. Eng. J. Med. 316:101-103, 1987.

Eschbach JW, Egrie JC, Downing MR, Browne JK, Adamson JW.

Correction of the anemia of end-stage renal disease with recombinant human erythropoietin: Results of a combined Phase I and Phase II clinical trial. N. Engl. J. Med. 316:73-78, 1987.

Eschbach JW, Browne JK, Delano BG, et al.

Results of a phase III, multicenter clinical trial with recombinant human erythropoietin in anemic patients with end-stage renal disease. (Submitted).

Ettenger R, Kerman R, Arnett J, et al.

Sensitization following donor-specific transfusions for living related renal transplantation. Transplant Proc. 15:943-945, 1983.

European Multicentre Trial.

Cyclosporin A as sole immunosuppressive agent in recipients of kidney allografts from cadaver donors. The Lancet 2:57-60, 1982.

European Multicentre Trial Group.

Cyclosporine in cadaveric renal transplantation: one year follow-up of a multicentre trial. The Lancet 1:986-989, 1983.

Evans RW.

Health care technology and the inevitability of resource allocation and rationing decisions (first of two parts). JAMA 249:2047-2053, 1983.

Evans RW.

Health care technology and the inevitability of resource allocation and rationing decision (second of two parts). JAMA 249:2208-2219, 1983.

Evans RW.

The need for and cost of liver transplantation in the U.S. Seattle, WA: Battelle Human Affairs Research Centers, 1984.

Evans RW.

Cyclosporine in cadaveric renal transplantation. N. Engl. J. Med. 311:127, 1984.

Evans RW.

The quality of life of patients with chronic renal disease: Comparison of four treatment modalities. In Kutner NG, Cardenas DD, Bower JD, eds., Rehabilitation and the Chronic Renal Disease Patient. New York: J. P. Medical and Scientific Books, 1985:61-83.

- Evans RW.
The socioeconomics of organ transplantation. Transplant Proc. 17(6) Suppl 4:129-136, 1985.
- Evans RW.
The heart transplant dilemma. Issues in Science and Technology 2(3):91-101, 1986.
- Evans RW.
Coverage and reimbursement for heart transplantation. Int. J. of Technology Assessment in Health Care 2:425-449, 1986.
- Evans RW.
Cost-effectiveness analysis of transplantation. Surg. Clinics of North America 66:603-616, 1986.
- Evans RW.
Public perception and the realities of organ transplantation. Michigan Hospitals 23(12):13-18, 1987.
- Evans RW.
A catastrophic disease perspective on organ transplantation. In: Ginzberg E., ed., Medicine and Society: Clinical Decisions and Societal Values. Boulder, CO: Westview Press, 1987:61-95.
- Evans RW.
The economics of heart transplantation. Circulation 75:63-76, 1987.
- Evans RW.
Medicare-designated centers for cardiac transplantation. N. Engl. J. Med. 317:966, 1987.
- Evans RW, Blagg CR, Bryan FA, Jr.
Implications for health care policy: a social and demographic profile of hemodialysis patients in the United States. JAMA 245:487-491, 1981.
- Evans RW, Manninen DL, Overcast TD, et al.
The National Heart Transplantation Study: Final Report. Seattle, WA: Battelle Human Affairs Research Centers, 1984.
- Evans RW, Manninen DL, Gersh BJ, et al.
The need for and supply of donor hearts for transplantation. Heart Transplantation 4:57-62, 1984.
- Evans RW, Hart LG, Manninen DL.
A comparative assessment of the quality of life of successful kidney transplant patients according to source of graft. Transplant Proc. 16:1353-1358, 1984.
- Evans RW, Manninen DL, Garrison LP Jr, et al.
The quality of life of patients with end-stage renal disease. N. Engl. J. Med. 312:553-559, 1985.

- Evans RW, Manninen DL.
Quality of life of patients with end-stage renal disease. N. Engl. J. Med. 312:1579-1580, 1985.
- Evans RW, Manninen DL, Maier A, Garrison LP Jr, Hart LG.
The quality of life of kidney and heart transplant recipients. Transplant Proc. 17:1579-1582, 1985.
- Evans RW, Yagi J.
Social and medical considerations affecting the selection of transplant recipients: the case of heart transplantation. In: Doudera AE, ed., Legal and Ethical Aspects of Organ Transplantation. Ann Arbor, MI: Health Administration Press, 1986.
- Evans RW, Manninen DL, Garrison LP Jr, Maier A.
Donor availability as the primary determinant of the future of heart transplantation. JAMA 255:1892-1898, 1986.
- Evans RW, Manninen DL.
Public Opinion Concerning Organ Donation, Procurement, and Distribution: Results of a National Probability Sample Survey. Seattle, WA: Battelle Human Affairs Research Centers, 1987.
- Evans RW, Manninen DL, Garrison LP, Jr., Hart LG.
Special Report: Findings From the National Kidney Dialysis and Kidney Transplantation Study. HCFA Publ. No. 03230. Baltimore, MD: Health Care Financing Administration, 1987.
- Evans RW, Manninen DL.
Cost of cyclosporine. The Lancet 2(8573):1472, 1987.
- Evans RW, Manninen DL, Maier AM.
Selected characteristics of 444 heart donors. Transplant Proc. 19(1): 2501-2502, 1987.
- Evans RW, Manninen DL.
Clinical immunosuppression. In: Evans RW, Manninen DL, Immunosuppressive Therapy Study. Seattle, WA Battelle Human Affairs Research Centers, 1988.
- Evans RW, Manninen DL.
Economic impact of cyclosporine in transplantation. Transplant Proc. 20(3):49-62, 1988.
- Evans RW, Manninen DL.
U.S. public opinion concerning the procurement and distribution of donor organs. Transplant Proc. 20(5):781-785, 1988.
- Evans RW, Manninen DL, Thompson C.
Kidney Transplant Immunosuppressive Protocols Study. Seattle, WA: Battelle Human Affairs Research Center, 1989.

- Fabre JW, Ting A.
Immunobiology of transplantation. In: Morris PJ (ed.), Kidney Transplantation: Principles and Practice. New York: Grune and Stratton, 1979:1-25.
- Farber B, Kaiser D, Wenzel R.
Relation between surgical volume and incidence of postoperative wound infection. N. Engl. J. Med. 305:200-203, 1981.
- Fassbinder W, Challah S, Brynger H.
Long-term results of renal transplantation in Europe. Transplant Proc. 19:3754-3757, 1987.
- Fazio AF.
A Concurrent Validation Study of the NCHS General Well-Being Schedule. Vital and Health Statistic Series, Series 2, Number 73, Publication No. (HRA) 78-1347. Hyattsville, MD: National Center for Health Statistics, 1977.
- Feduska NJ, Melzer J, Amend W, et al.
Dramatic improvement in the success rate for renal transplants in diabetic recipients with donor-specific transfusions. Transplantation 38:704-708, 1984.
- Feduska NJ, Melzer J, Amend WJC, et al.
Clinical management of immunosuppressive therapy for cyclosporine-treated recipients of cadaver kidney transplants at one to six months. Transplant Proc. 18(Suppl. 1):136-140, 1986.
- Feduska NJ, Melzer JS, Amend WJC, et al.
Cyclosporine provides better success for both higher- and lower-risk cadaveric kidney transplant recipients. Transplant Proc. 20(3)(Suppl. 3):102-109, 1988.
- Feinstein AR.
Clinical Epidemiology: The Architecture of Clinical Research. Philadelphia, PA: WB Saunders, 1985.
- Ferguson RM.
A multicenter experience with sequential ALG/cyclosporine therapy in renal transplantation. Clin. Transplantation 2:285-294, 1988.
- Ferguson RM, Henry M, Sommer BG, et al.
A single center experience with cyclosporine in renal transplantation: Ohio State University 1983 to 1987. In: Terasaki PI (ed.), Clinical Transplants, 1987. Los Angeles, CA: UCLA Tissue Typing Laboratory, 1987:195-207.
- Ferguson RM, Rynasiewicz JJ, Sutherland DER, et al.
Cyclosporine A in renal transplantation: a prospective randomized trial. Surgery 92:175-182, 1982.

- Finkelstein SN, Isaacson KA, Frishkopf JJ.
The process of evaluating medical technologies and third party coverage. J. Health Care Technol. 1:89-102, 1984.
- Finkler SA.
Cost-effectiveness of regionalization: the heart surgery example. Inquiry 16:266, 1979.
- Finkler SA.
Cost-effectiveness of regionalization: further results for heart surgery. Health Services Research 16:325-333, 1981.
- First MR, Alexander JW, Wadhwa N, et al.
The use of low doses of cyclosporine, azathioprine, and prednisone in renal transplantation. Transplant Proc. 18(Suppl. 1):132-135, 1986.
- Fish JC, Flye MW, Williams A, et al.
Inability of thoracic duct drainage to prevent hyperacute rejection. Transplantation 36:134-138, 1983.
- Flechner SM.
Cyclosporine: a new and promising immunosuppressive agent. Urologic Clinics of North America. 10:263-275, 1983.
- Flechner SM, Novick AC, Braun WE, et al.
Functional capacity and rehabilitation of recipients with functioning renal allograft for ten years or more. Transplantation 35:572-576, 1983.
- Flechner S, Van Buren C, Kerman R, Kahan B.
The effect of conversion from cyclosporine to azathioprine immunosuppressive for intractable nephrotoxicity. Transplant Proc. 15(Suppl. 1):2869, 1983.
- Flechner SM, Kerman RH, van Buren CT, Epps L, Kahan BD.
The use of cyclosporine in living-related renal transplantation; donor-specific hyporesponsiveness and steroid withdrawal. Transplantation 38:685, 1984.
- Flechner SM, Lorber M, Van Buren C, et al.
The case against conversion to azathioprine in cyclosporine-treated renal recipients. Transplant Proc. 17(Suppl. 1):276-281, 1985.
- Flechner SM, Van Buren CT, Jarowenko M, et al.
The fate of patients converted from cyclosporine to azathioprine to improve renal function. Transplant Proc. 17:1227-1230, 1985.
- Fletcher RH, Fletcher SW, Wagner EG.
Clinical Epidemiology: The Essentials. 2nd edition. Baltimore, MD: Williams and Wilkins, 1988.

- Flood AB, Scott WR, Ewy W.
Does practice make perfect? Part I. The relation between hospital volume and outcomes for selected diagnostic categories. Med. Care 22: 98-114, 1984.
- Flood AB, Scott WR, Ewy W.
Does practice make perfect? Part II: The relation between volume and outcomes and other hospital characteristics. Med. Care 22:115-125, 1984.
- Flores JC, Callender CO.
Kidney transplant rehabilitation at Harvard University Hospital: a retrospective analysis. Transplant Proc. 19(2 Suppl 2):115-117, 1987.
- Ford HR, Fryd DS, Canafax DM, et al.
Adjunctive azathioprine and antilymphocyte serum immunosuppression with cyclosporine. Transplant Proc. 20(3)(Suppl. 3):8-12, 1988.
- Foster MS, Wenham PW, Cooksey GD, Paterson AD et al.
Treatment of poor prognosis renal allograft rejection with anti-lymphocyte globulin (ALG)--An analysis of late results. Clin. Transplantation 2:240-244, 1988.
- Fowler FJ, Wennberg JE, Timothy RP, et al.
Symptom status and quality of life following prostatectomy. JAMA 259: 3018-3022, 1988.
- Fox M.
Suppression of tissue immunity by cyclophosphamide. Transplantation 2:475, 1964.
- Friedman LM, Furberg CD, DeMets DL.
Fundamentals of Clinical Trials. Boston, MA: John Wright, PSG Inc., 1981.
- Fries D, Kechrid C, Charpentier B, et al.
A prospective study of a triple association: cyclosporine, corticosteroids, and azathioprine in immunologically high-risk renal transplantation. Transplant Proc. 15:1231-1234, 1985.
- Fries D, Hiesse C, Charpentier B, et al.
Triple combination of low-dose cyclosporine, azathioprine, and steroids in first cadaver renal allografts. Transplant Proc. 19:1911-1914, 1987.
- Fries D, Hiesse C, Santelli G, et al.
Triple therapy with low-dose cyclosporine, azathioprine, and steroids: long-term results of a randomized study in cadaveric donor renal transplantation. Transplant Proc. 20(3)(Suppl. 3):130-135, 1988.
- Frisk B, Persson H, Wedel N, et al.
Study of 172 patients at 20 to 21 years after renal transplantation. Transplant Proc. 19:3769-3771, 1987.

- Fuchs VR.
The "competition revolution" in health care. Health Affairs 7(3):5-24, 1988.
- Fuller AK, Fuller AE, Yates LE.
The use of child restraint devices in vehicles. JAMA 255:614, 1986.
- Garner TI, Dardis R.
Cost-effectiveness of end-stage renal disease treatments. Med. Care 25: 25-34, 1987.
- Germuth FG, Ottinger B.
Effects of 17-hydroxy-11-dehydrocorticosterone (compound E) and of ACTH on Arthus reaction and antibody formation in the rabbit. Proc. Soc. Exp. Biol. Med. 74:815, 1950.
- Gianello P, Squifflet JP, Pirson Y, et al.
Cyclosporine-steroids versus conventional therapy in cadaver kidney transplantation: analysis of a randomized trial at two years. Transplant Proc. 19:1867-1872, 1987.
- Gilson BS, Bergner M, Bobbitt RA, Carter WB.
The Sickness Impact Profile: Final development and testing. Discussion paper number 14. Seattle, WA: Center for Health Services Research, Department of Health Services, University of Washington, 1979.
- Ginsberg PB, Hammons GT.
Competition and the quality of care: the importance of information. Inquiry 25(1):108-115, 1988.
- Glass NR, Miller DT, Sollinger H, Belzer FO.
A four-year experience with donor blood transfusion protocols for living-donor renal transplantation. Transplantation 39:615-619, 1985.
- Goeken N.
Survey on Transplantation Practices, American Society of Transplant Surgeons. Rockville, MD: Office of Organ Transplantation, June, 1985.
- Goldbaum G.
The use of seat belts. JAMA 257:1473-1474, 1987.
- Goldstein G.
Therapeutic use of the monoclonal antibody Orthoclone OKT-3. Transplant Proc. 19(2)(Suppl.1):1-58, 1988.
- Goldworth A.
The moral limit to private profit in entrepreneurial science. Hastings Cent. Rpt. 17(3):8-10, 1987.
- Gonwa TA, Nghiem DD, Schulak JA, Corry RJ.
Results of conversion from cyclosporine to azathioprine in cadaveric renal transplant. Transplantation 43:225-228, 1987.

- Gordon RD, Starzl TE, Hakala TR, et al.
Long-term results of cyclosporine-steroid therapy in 131 non-matched cadaveric renal transplants. Clin. Transplantation. 1:44-48, 1987.
- Gornick M, Greenberg JN, Eggers PW, Dobson A.
Twenty years of Medicare and Medicaid: Covered populations, use of benefits, and program expenditures. Health Care Financing Review 1985 Annual Supplement 13-59, 1985.
- Gottlieb MN, Tilney NL, Lazarus JM.
Endocrine dysfunction in chronic renal failure. In: Tilney NL, Lazarus JM, eds., Surgical Care of the Patient with Renal Failure. Philadelphia, PA: W.B. Saunders, 1982:125-134.
- Goto T, Kino T, Hatanaka H et al.
Discovery of FK-506, a novel immunosuppressant isolated from *Streptomyces tsukubaensis*. Transplant Proc. 19(5)(Suppl 6):4-8, 1987.
- Grant O, Stiller C, Duff J, et al.
Experience of a Canadian multi-organ transplant service. Can. Med. Assoc. J. 135: 197-203, 1986.
- Grapin C, Michel B, Charpenter B, et al.
Long-term prognosis of renal transplantation: a retrospective study of 90 patients living more than 10 years with a functioning allograft. Transplant Proc. 19:3765-3766, 1987.
- Greenberg B, Derzon RA.
Determining health insurance coverage of technology: problems and options. Med. Care 19:967-978, 1981.
- Greenfield S, Aronow HV, Elashoff RM, Watanabe D.
Flaws in mortality data. JAMA 260:2253-2255, 1988.
- Greger B, Reis HJ, Mellert J, et al.
Rejection treatment by polyclonal antibodies in kidney transplantation: reliable therapy without severe side-effects. Transplant Proc. 20 (5) (Suppl 6):9-11, 1988.
- Grenfell A, Migdalis I, Leslie DG.
Short stature and diabetic complications. Transplant Proc. 18:1500, 1986.
- Griffin PJA, Ross WB, Williams JD, Salaman JR.
Low-dose cyclosporine monotherapy in renal transplantation. Transplant Proc. 19:3685-3686, 1987.
- Griffith BP, Hardesty RL, Kormos RL, Trento A, Borovetz HS, Thompson ME, Bahnson HT.
Temporary use of the Jarvik-7 total artificial heart before transplantation. N. Engl. J. Med. 316:130-134, 1987.

- Grino JM, Castela AM, Sabate I, et al.
Low-dose cyclosporine, ALG, and steroids in first cadaveric renal transplant. Transplant Proc. 19:3674-3676, 1987.
- Groth CG.
There is no need to give blood transfusions as pretreatment for renal transplantation in the cyclosporine era. Transplant Proc. 19:153-154, 1987.
- Groth CG, ed.
Pancreatic Transplantation. Philadelphia: WB Saunders, 1988.
- Grunfeld JP, Kleinknecht D, Moreau JF, et al.
Permanent hypertension after renal hemotransplantation in man. Clin. Sci. Mol. Med. 48:391, 1975.
- Guerin D, MacKinnon DP.
An assessment of the California child passenger restraint requirement. Am. J Public Health 75:142-144, 1985.
- Gunby P.
Organ transplant group formed. JAMA 250:2103, 1983.
- Gutman RA, Stead WW, Robinson RR.
Physical activity and employment status of patients on maintenance dialysis. N. Engl. J. Med. 304:309-313, 1981.
- Guttmann RD.
Renal transplantation (second of two parts). N. Engl. J. Med. 301:975-981, 1979.
- Hakala TR, Starzl TE, Rosenthal JT et al.
Cadaveric renal transplantation with cyclosporin-A and steroids. Transplant Proc. 15:465-470, 1983.
- Halasz NA, Gamboa EA, Ward DM, Steiner RW, Bronshter OL.
Kidney transplantation in the cyclosporine era. Arch. Surg. 122:1001-1004, 1987.
- Hall BM.
Cyclosporine and immunosuppressive regimens in renal transplantation. N. Engl. J. Med. 319:1288, 1988.
- Hall BM, Tiller DJ, Hardie I, et al.
Comparison of three immunosuppressive regimens in cadaver renal transplantation: long-term cyclosporine, short-term cyclosporine followed by azathioprine and prednisolone without cyclosporine. N. Engl. J. Med. 318:1499-1507, 1988.

- Halloran P, Ludwin D, Aprile M, et al.
Randomized comparison between cyclosporine and conventional therapy plus Minnesota antilymphocyte globulin in cadaveric renal transplantation. Transplant Proc. 15(Suppl 1 and 2):2513-1516, 1983.
- Halloran P, Ludwin D, Aprile M, et al.
Comparison of antilymphocyte globulin-imuran, cyclosporine, and antilymphocyte globulin-cyclosporine therapy for cadaver renal transplantation. Transplant Proc. 17:1201-1203, 1985.
- Halloran P, Ludwin D, Bear R, et al.
Intermodal immunosuppression for cadaver renal transplantation: results using antilymphocyte globulin, azathioprine, cyclosporine, and prednisone. Transplant Proc. 19:1931-1932, 1987.
- Hamburger J.
Transplantation immunology: In: Hamburger J, Crosnier J, Bach J-F, Kreis H. (eds), Renal Transplantation: Theory and Practice. 2nd edition. Baltimore, MD: Williams and Wilkins, 1981:1-22.
- Harford AM, Shopp GM, Ashmore LM, et al.
OKT-3-treated kidney transplant patients: monitoring of effects on peripheral blood mononuclear cells by using two-flow cytometry. Transplant Proc. 20(Suppl. 1):245-248, 1988.
- Harrison MR.
Organ procurement for children: the anencephalic fetus as donor. The Lancet 2 (8520):1383-1386, 1986.
- Hart LG, Evans RW.
The functional status ESRD patients as measured by the Sickness Impact Profile. J. Chron. Disease 40 (Suppl 1):117s-130s, 1987.
- Health Care Financing Administration.
Research Report: End-Stage Renal Disease, 1985. HCFA Pub. No. 03274. Baltimore, MD: Health Care Financing Administration, 1987.
- Health Care Financing Administration.
Research Report: End-Stage Renal Disease, 1986. Baltimore, MD: Health Care Financing Administration, 1988.
- Health Insurance Association of America.
Survey of Reimbursement Practices for Experimental Procedures and Organ Transplants Under Group Major Medical Expense Plans. Research and Statistical Bulletin No. 3-83. New York, NY: Health Insurance Association of America, 1983.
- Health Insurance Association of America.
Organ Transplants and Their Implications for the Health Insurance Industry. Washington DC: Public Relations Division, HIAA, 1985.

Health insurer is selecting hospitals for transplants.

New York Times, July 28, 1988.

Hearings before the Subcommittee on Investigations and Oversight of the Committee of Science and Technology, United States House of Representatives.

Procurement and Allocation of Human Organs for Transplantation. Ninety-Eighth Congress, November 7, 9, 1983. No. 71, Washington DC: Government Printing Office, 1984.

Hedges L, Olkin I.

Statistical Methods for Meta-Analysis. New York: Academic Press, 1985.

Held PJ, Pauly MV, Bovbjerg RR, et al.

Access to kidney transplantation: has the United States eliminated income and racial differences? Arch. Intern. Med. 748:2594-2600, 1988.

Hellinger FJ.

An analysis of a public program for heart transplantation. J. Hum. Resources 17:307-313, 1982.

Hellinger FJ.

Status of insurance coverage for organ transplants in the United States: a review of recent surveys. Int. J. of Technology Assessment in Health Care 2:563-570, 1986.

Henny FC, Kootte AMM, Van Bockel JH, et al.

A prospective study on the influence of cyclosporine and azathioprine on renal allograft survival and function. Transplant Proc. 19:1853-1955, 1987.

Henriksen I, Hansen BL, Birkeland SA.

Conversion of long-term renal allograft recipients from prednisolone/azathioprine to cyclosporine. Transplant Proc. 18:1002-1004, 1986.

Henry ML, Sommer BG, Ferguson RM.

Beneficial effects of cyclosporine compared with azathioprine in cadaveric renal transplantation. Am. J. Surg. 150:533-536, 1985.

Henry ML, Sommer BG, Ferguson RM.

The impact of cyclosporine compared with azathioprine for cadaveric renal transplant immunosuppression. Transplant Proc. 17:1244-1246, 1985.

Henry ML, Sommer BG, Ferguson RM.

Triple drug therapy: an alternative regimen in renal transplantation. Transplant Proc. 19:1920-1921, 1987.

- Hiesse C, Charpentier B, Hiesse C.
Safety of triple immunosuppressive treatment (cyclosporine, azathioprine, and prednisolone). The Lancet 2(8468):1355, 1985.
- Hingson R, Levenson SM, Heeren T, et al.
Repeal of the Massachusetts seat belt law. Am. J. Public Health. 78:548-552, 1988.
- Hoelm RJ, Simmons RL.
Immunosuppressive drugs combined with heterologous antilymphocyte serum for allograft prolongation. Transplantation. 5:1409, 1967.
- Hoitsma AJ, van Lier HJJ, Wetzels JFM, Berden JHM, Koene RAP.
Cyclosporine treatment with conversion after three months versus conventional immunosuppression in renal allograft recipients. The Lancet 1(8533):584-586, 1987.
- Hoitsma AJ, Wetzels JFM, Berden HME, Koene RAP.
Antirejection treatment with anti-thymocyte globulin in renal transplant recipients treated with cyclosporine as basic immunosuppression. Transplant Proc. 20(5)(Suppl 6):12-13, 1988.
- Hoitsma AJ, Tiggeler RWG, Wetzels JFM, et al.
Cyclosporine treatment with conversion after three months is a safe protocol in renal allograft recipients. Transplant Proc. 20(3)(Suppl. 3):161-163, 1988.
- Holzer BR, Gluck Z, Zambelli D, Fey M.
Transmission of malaria by renal transplantation. Transplantation 39: 315-316, 1985.
- Hourmant M, Souillou JP, Guenel J.
Comparison of three immunosuppressive strategies in kidney transplants: antithymocyte globulin and conventional treatment, antithymocyte globulin and cyclosporine, and cyclosporine. A one-center randomized study. Transplant Proc. 17:1158-1161, 1985.
- Hoyt E, Grant RC, Hahberg ME, Billingham, et al.
Analysis of the immunosuppressive and nephrotoxic effects of cyclosporine. G. J. Heart Transplantation. 7:111-118, 1988.
- Hull AR, Atkins CR, Brinker KR, et al.
Dallas experience with cyclosporine A (CsA) one to six months posttransplant. Transplant Proc. 18(Suppl 1):128-131, 1986.
- Hunt SM, McEwen J.
The development of a subjective health indicator. Social Health Illness 2:231-245, 1983.
- Hunt SM, McEwen J, McKenna SP.
Measuring Health Status. Beckenham, Kent: Croom Helm, 1986.

- Hutchinson TA, Boyd NF, Feinstein AR.
Scientific problems in clinical scales, as demonstrated by the Karnofsky index of performance status. J. Chronic Dis. 32:661-666, 1979.
- Ibels LS, Alfrey AC, Huffer WE, Weil R.
Aseptic necrosis of bone following renal transplantation: Experience in 194 transplant recipients and review of the literature. Medicine 57:25, 1978.
- Iglehart JK.
Health policy report: Funding the End-Stage Renal Disease Program. N. Engl. J. Med. 306:492-496, 1982.
- Iglehart JK.
Federal policies and the poor. N. Engl. J. Med. 307:836-840, 1982.
- Iglehart JK.
Transplantation: the problem of limited resources. N. Engl. J. Med. 309:123-128, 1983.
- Iglehart JK.
The politics of transplantation. N. Engl. J. Med. 310:864-868, 1984.
- Iglehart JK.
Medical care of the poor -- a growing problem. N. Engl. J. Med. 313:59-63, 1985.
- Illner W-D, Land W, Habersetzer R, et al.
Cyclosporine in combination with azathioprine and steroids in cadaveric renal transplantation. Transplant Proc. 17:1181-1184, 1985.
- Intergovernmental Health Policy Project.
Medicaid Coverage and Payment Policies for Organ Transplants: A Fifty State Review. Washington, D.C.: George Washington University, 1985.
- Intergovernmental Health Policy Project.
Medicaid Coverage and Payment Policies for Organ Transplants: Findings of a National Survey. Washington, D.C.: George Washington University, 1988.
- International Medical Tribune Syndicate.
Health insurer designates hospitals for transplants. The Nation's Health 18(9):22, 1988.
- Jacobsen JE, Pontin A, van Zyl-Smit R, et al.
Results of conversion immunosuppression in 193 cadaver and 42 living-related donor renal allografts. Transplant Proc. 20(3)(Suppl. 3):155-156, 1988.
- Jain AB, Buckels JAC, Adu D, et al.
Long-term results of cyclosporine in cadaveric renal transplantation from a single center. Transplant Proc. 20(3)(Suppl. 3):82-85, 1988.

- James K.
Antilymphocyte antibody: a review. Clin. Exp. Immunol. 2:615, 1967.
- Jelly JT.
Assessing quality. JAMA 260: 2715-2716, 1988.
- Jencks SF, Williams DF, Kay TL.
Assessing hospital-associated deaths from discharge data. JAMA 260:2240-2246, 1988.
- Jencks SF, Daley J, Draper D et al.
Interpreting hospital mortality data. JAMA 260:3611-3616, 1988.
- John RWG, Wise MH, Bakran A, et al.
A four-year prospective study of cyclosporine in cadaver renal transplantation. Transplant Proc. 17:1197-1200, 1985.
- Johnson RWG.
Cyclosporine in cadaveric renal transplantation: three-year follow-up of a European Multicentre trial. Transplant Proc. 18:1229-1233, 1986.
- Johnson WC, Nabseth DC.
Pancreatitis in renal transplantation. Ann. Surg. 171:309, 1970.
- Johnson JP, McCauley CR, Copley JB.
The quality of life of hemodialysis and transplant patients. Kidney Int. 22:286-291, 1982.
- Jonasson O.
In organ transplants, Americans first? Commentary. Hastings Center Report 16(5):25, 1986.
- Jones RM, Murie JA, Allen R, et al.
Immunosuppression with cyclosporine, azathioprine, and prednisolone in cadaver renal allograft recipients. Transplant Proc. 19:1927-1930, 1987.
- Joyce, LD, Johnson KE, Pierce WS, et al.
Summary of the world experience with clinical use of total artificial hearts as heart support devices. J. Heart Transplant. 5:229-235, 1986.
- Kahn KL, Brook RH, Draper D., et al.
Interpreting hospital mortality data. JAMA 260:3625-2628, 1988.
- Kahan BD.
The impact of CSA therapy. Transplantation and Immunology Letter 4(4):1, 15, 1988.
- Kahan BD.
Cyclosporine and transplantation: a review of the Second International Congress. Transplantation and Immunology Letter 4(Congress Summary):2-4, 1988.

- Kahan BD, Flechner SM, Lorber MI, et al.
Complications of cyclosporine-prednisone immunosuppression in 402 renal allograft recipients exclusively followed at a single center for from one to five years. Transplantation 43(2):197-204, 1987.
- Kahan BD, Kerman RH, Wideman CA, et al.
Impact of cyclosporine on renal transplant practice at the University of Texas Medical School at Houston. Am. J. Kidney Dis. 5:288-295, 1985.
- Kahan BD, Van Buren CT, Flechner SM, et al.
Cyclosporine immunosuppression mitigates immunologic risk factors in renal allotransplantation. Transplant Proc. 15(4)(Suppl. 1):2469-2478, 1983.
- Kahan BD, Van Buren CT, Lin S, et al.
Immunopharmacologic monitoring of cyclosporin A treated recipients of cadaveric kidney allografts. Transplantation 34:36, 1982.
- Kalman TP, Wilson PG, Kalman CM.
Psychiatric morbidity in long-term renal transplant recipients and patients undergoing hemodialysis. A comparative study. JAMA 250:55-58, 1983.
- Kanoti GA.
Ethical considerations in solid organ pediatric transplants. Transplant Proc. 18(3)(Suppl 2):43-46, 1986.
- Karrer FM, Mammana RB, Copeland JG.
Survival following pancreatitis and surgical drainage of a pancreatic pseudocyst in a heart transplant recipient. Heart Transplant 1:325-328, 1982.
- Kashiwagi N, Brantignan CO, Brettschneider L, Groth CG, Starzl TE.
Clinical reactions and serologic changes after the administration of heterologous antilymphocyte globulin to human recipients of renal homografts. Ann. Intern. Med. 68:275, 1968.
- Kastiel DL.
Insurers want controls on transplant costs. Business Insurance, November 4, 1985.
- Kay HEM.
Immunosuppression and the risk of brain lymphoma. N. Engl. J. Med. 208:1099, 1983.
- Kelly JV, Hellinger FJ.
Physician and hospital factors associated with mortality of surgical patients. Med. Care. 24:785-800, 1986.

- Kenzora JE, Tilney NL.
Musculoskeletal abnormalities in dialysis and transplant patients. In: Tilney NL, Lazarus HJM, eds., Surgical Care of the Patient with Renal Failure. Philadelphia, PA: W.B. Saunders, 1982:147-162.
- Keown PA.
Canadian transplant study group. Examination of parameters influencing the benefit/detriment ratio of cyclosporine in renal transplantation. Am. J. Kidney Dis. 5:328-332, 1985.
- Keown PA.
Important considerations in conversion from cyclosporine to azathioprine following renal transplantation. Literature Scan: Transplantation. 3(2):1-2, 1987.
- Keown PA.
The Second International Congress on Cyclosporine, Washington, D.C., November 4-7, 1987. Literature Scan: Transplantation. 3(4):1-2, 32, 1988.
- Keown PA, Stiller CR, Ulan RA, et al.
Immunological and pharmacological monitoring in the clinical use of Cyclosporin A. The Lancet 1:686, 1981.
- Keown PA, Stiller CR.
Dialysis or transplant: an integrated approach to end-stage kidney disease management. Kidney Int. Suppl. 24:s145-s149, 1988.
- Kerman RH, Van Buren CT, Payne W, Flechner S, Agostino G, Conley S, Brewer E, Kahan BD.
The influence of pretransplant blood transfusions from random donors on immune parameters affecting cadaveric allograft survival. Transplantation 36:50-53, 1983.
- Khauuli RB, Steinmuller DR, Novick AC, et al.
A critical look at survival of diabetics with end-stage renal disease: Transplantation versus dialysis therapy. Transplantation 41:598-602, 1986.
- Kinlen L, Doll R, Peto J.
The incidence of tumors in human transplant recipients. Transplant Proc. 15:1039-1043, 1983.
- Kirkman RL, Strom TB, Weir MR, Tilney NL.
Late mortality and morbidity in recipients of long-term renal allografts. Transplantation 34:347, 1982.
- Kirkpatrick CH.
Transplantation immunology: clinical aspects. JAMA 248:2727-2733, 1982.
- Kirkpatrick CH.
Transplantation immunology. JAMA 258:2993-3000, 1987.

- Kjellstrand CM.
Giving life -- giving death. Ethical problems of high technology medicine. Acta. Med. Scand. Suppl. 725:1-88, 1988.
- Kjellstrand CM.
Side effects of steroids and their treatment. Transplant Proc. 7:123-129, 1975.
- Kleinig JJ.
In organ transplants, Americans first? Commentary. Hastings Center Report 16(5):24-25, 1986.
- Knox RA.
Heart transplants: to pay or not to pay. Science 209:570-575, 1980.
- Kolata G.
Drug transforms transplant medicine. Science 221:40-42, 1983.
- Koote AMM, Lensen LM, van Bockel JH, Paul LC.
A randomized study comparing high- and low-dose regimens of cyclosporine in renal transplantation. Transplant Proc. 20(3)(Suppl. 3):136-139, 1988.
- Kountz SL, Cohn R.
Prolonged survival of a renal homograft by simultaneous splenectomy and hemotransplantation. Surg. Forum. 13:59, 1962.
- Krakauer H.
Immunosuppressants in Renal Transplantation: A Special Report Prepared for the Office of Organ Transplantation. Rockville, MD: Office of Organ Transplantation, Health Resources and Services Administration, 1985.
- Krakauer H.
Assessment of alternative technologies for the treatment of end-stage renal disease. Isr. J. Med. Sci. 22:245-259, 1986.
- Kramer MS, Shapiro SH.
Scientific challenges in the application of randomized trials. JAMA 252:2739-2745, 1984.
- Krohn P.
The influence of the spleen on the homograft reaction. Transplant Bull. 1:21, 1953.
- Krupp P, Gulick A, Timonen P.
Side effects and safety of Sandimmune in long-term treatment of renal transplant patients. Transplant Proc. 18:991-992, 1986.
- Kung PC, Goldstein G, Reinberg EL, et al.
Monoclonal antibodies defining distinctive human T cell surface antigens. Science 206:347, 1979.

- Kutner NG.
Quality of life of patients with end-stage renal disease. N. Engl. J. Med. 312:1579, 1985.
- Kutner NG.
Issues in the application of high cost medical technology: the case of organ transplantation. J. Health and Social Behavior 28:23-36, 1987.
- Kutner NG, Brogan D, Kutner MH.
End-stage renal disease treatment modality and patients' quality of life. Longitudinal assessment. Am. J. Nephrol. 6:396-402, 1986.
- Lacombe M.
Arterial stenosis complicating renal allotransplantation in man. A study of 38 cases. Ann. Surg. 181:283, 1975.
- Ladowski JS, Rosenthal TS, Taylor RJ.
The effect of previous sensitization on allograft survival with cyclosporine immunosuppression. Transplant Proc. 18:1218, 1985.
- Lafferty WE, Hopkins, SG, Honey J, et al.
Hospital charges for people with AIDS in Washington State: Utilization of a statewide hospital discharge data base. Am. J. Public Health 78: 949-952, 1988.
- Land W.
Use of cyclosporine in clinical kidney transplantation. Sandoz Symposium, Osaka, Japan, September, 1985.
- Land W, (ed.)
Optimal Use of Sandimmune in Organ Transplantation. Berlin: Springer-Verlag, 1987.
- Land W, Castro L, Hillebrand G, Gunther K, Gokel J.
Conversion rejection consequences by changing the immunosuppressive therapy for cyclosporine to azathioprine after kidney transplantation. Transplant Proc. 15(Suppl.1):2857-2861, 1983.
- Land W, Hammer C, Brynger H, eds.
Indications for Organ Transplantation. Transplant Proc 18(4) Supplement 3:1-102, 1986.
- Land W for the European Multicentre Trial Group.
Cyclosporine in cadaveric renal transplantation: five-year follow-up results of the European Multicentre Trial. Transplant Proc. 20(3)(Suppl.3):73-77, 1988.
- Larsson O.
Kidney transplantation in diabetic renal failure. A clinical and physiological study. Scand. J. Urol. Nephrol. Suppl. 95:1-84, 1985.

- Larsson D., Altman PO, Blohme I, et al.
Morbidity and mortality in diabetic and nondiabetic recipients of living related donor kidneys. Nephrol. Dial. Transplant 2(2):109-116, 1987.
- Latimer EA, Lave LB.
Initial effects of the New York State auto safety belt law. Am. J. Public Health 77:183-186, 1987.
- Laudicina SS.
State health risk pools: insuring the "uninsurable." Health Affairs 7(4):97-104, 1988.
- Laupacis A and the Canadian Transplant Study Group.
Complications of cyclosporine therapy -- a comparison to azathioprine. Transplant Proc. 15(Suppl. 1 and 2):2748-2753, 1983.
- Laupacis A, Sackett DL, Roberts RS.
An assessment of clinically useful measures of the consequences of treatment. N. Engl. J. Med. 318:1728-1733, 1988.
- Lawson LM.
Civilian Health and Medical Program of the Uniformed Services (CHAMPUS); Liver Transplantation. Federal Register 50(22):26222-26224, 1985.
- Lefrancois N, Pouteil-Noble C, Touraine JL, Dubernard JM, Traeger J.
Cyclosporine and prednisone v azathioprine, prednisone, and antilymphocyte globulin in 33 second kidney transplant recipients. Transplant Proc. 18:1259-1260, 1986.
- Lefrancois N, Elmghabbar N, Chosseiros P, et al.
Long-term results in kidney transplantation; patient and graft survival, causes of graft failure and mortality, renal function and complications after 10 years. Transplant Proc. 19:3767-3768, 1987.
- Lenfant C.
The process of evaluating the artificial heart. Hastings Cent. Rpt. 16(6):27, 1986.
- Lennard TWJ, Venning M.
Cyclosporine forever? The Lancet 1:1149, 1986.
- Lennard TWJ, Venning M, Donnelly PK, et al.
Conversion of immunosuppression in renal allograft recipients from cyclosporin A to azathioprine and prednisolone 6 months after transplantation. Transplant Proc. 19:3594-3596, 1987.
- Levin B, Collins G, Waer M, et al.
Treatment of cadaveric renal transplant recipients with total lymphoid irradiation, antilymphocyte globulin, and low dose prednisone. The Lancet 2(8468):1321-1324, 1985.

- Light JA, Mertz SJ, Oddenino K.
Donor-specific transfusion with minimal sensitization. Transplant Proc. 15:917-923, 1984.
- Light JA, Aquino A, Ali A, Rodriquez R, Ali S.
Quadruple drug therapy prevents graft loss from acute rejection without increasing mortality. Transplant Proc. 19:1927-1930, 1987.
- Light R, Pillemer D.
Summing Up: The Science of Reviewing Research. Cambridge, MA: Harvard University Press, 1984.
- Lohr KN.
Outcome measurement: concepts and questions. Inquiry 25:37-50, 1988.
- Lohr KN, Yordy KD, Thier SO.
Current issues in quality of care. Health Affairs 7(1):5-18, 1988.
- Loisance DY, Dcleuze P, Kawasaki K, et al.
Total artificial heart as a bridge to retransplantation in acute cardiac rejection. J. Heart Transplant 6:281-285, 1987.
- Longmire WP, Mellinkoff SM.
Regionalization of operations. N. Engl. J. Med. 301:1393-1394, 1979.
- Lorber MI, Flechner SM, van Buren CT, et al.
Cyclosporine toxicity, the effect of combined therapy using cyclosporine, azathioprine, and prednisone. Am. J. Kid. Dis. 9:476-484, 1987.
- Lorber MI, Van Buren CT, Flechner SM, Williams C, Kahan BD.
Hepatobiliary and pancreatic complications of cyclosporine therapy in 466 renal transplant recipients. Transplantation 43:35-40, 1987.
- Lowrie EG, Lazarus JM, Mocelin AJ, et al.
Survival of patients undergoing chronic hemodialysis and renal transplantation. N. Engl. J. Med. 288:863-867, 1973.
- Lucas BA, Vaughn WK, Spees EK, Sanfilippo F.
Identification of donor factors predisposing to high discard rates of cadaver kidneys and increased graft loss within one year posttransplantation. SEOPF 1977-1982. Transplantation 43(2):249-252, 1987.
- Ludbrook A.
A cost-effectiveness analysis of the treatment of chronic renal failure. Applied Economics 13:337-350, 1981.
- Luft HS.
The relation between surgical volume and mortality: an exploration of causal factor and alternative models. Med. Care. 18:940-959, 1980.

- Luft HS.
Regionalization of medical care. Am. J. Public Health 75:125-126, 1985.
- Luft HS, Bunker JP, Enthoven AC.
Should operations be regionalized? The empirical relation between surgical volume and mortality. N. Engl. J. Med. 301:1364-1369, 1979.
- Luft HS, Robinson JC, Garnick DW, Maerki SC, McPhee SJ.
The role of specialized clinical services in competition among hospitals. Inquiry 23(1):83-94, 1986.
- Luft HS, Hunt SS.
Evaluating individual hospital quality through outcome statistics. JAMA 255:2780-2784, 1986.
- Lundgren G, Albrechtsen D, Flatmark A, et al.
HLA matching and pretransplant blood transfusions in cadaveric renal transplantation -- a changing picture with cyclosporine. The Lancet 2(8497):66-69, 1986.
- Lundgren G, Groth CG, Albrechtsen D.
HLA-matching and pretransplant blood transfusions in cadaveric renal transplantation -- a changing picture with cyclosporine. The Lancet 2(8498):66-69, 1986.
- Lundgren G, Albrechtsen D, Brynger H, et al.
Role of blood transfusions and HLA matching in cyclosporine-treated renal transplant recipients: a Scandinavian multicentre study. Transplant Proc. 18:1248-1255, 1986.
- Lundgren G, Albrechtsen D, Brynger H, et al.
Improved early course after cadaver renal transplantation by reducing the cyclosporine dose and adding azathioprine. Transplant Proc. 19:2074-2079, 1987.
- MacDonald AS, Belitzky P, Gupta R, et al.
Conversion from cyclosporine to azathioprine in renal allograft recipients. Transplant Proc. 17:1940-1942, 1985.
- MacDonald AS, Daloze P., Dandavino R, et al.
A randomized study of cyclosporine with and without prednisone in renal allograft recipients. Transplant Proc. 19:1865-1866, 1987.
- Macek C.
Cyclosporine's acceptance heralds new era in immunopharmacology. JAMA 250:449-455, 1983.
- Maddrey WC, ed.
Transplantation of the Liver. New York: Elsevier, 1988.

- Maddux MS, Veremis SA, Bauma WD, Pollak R, Mozes MF.
Conversion from cyclosporine to azathioprine after renal transplantation: long-term effects on renal function, rejection, and allograft survival. Transplant Proc. 20(3)(Suppl. 3):152-154, 1988.
- Mann LM
A group approach to teaching and support in a small transplant unit. ANNA J. 12:102-105, 1985.
- Manninen DL, Evans RW.
Public attitudes and behavior regarding organ donation. JAMA 253:3111-3115, 1985.
- Manninen DL, Evans RW.
The costs and outcomes of kidney transplantation according to initial immunosuppressive drug protocol. In: Terasaki PI (ed.), Clinical Transplants, 1987. Los Angeles, CA: UCLA Tissue Typing Laboratory, 1987:269-275.
- Marchioro TL, Extell HK, La Via MF, Waddell WR, Starzl TE.
The role of adrenocortical steroids in reversing established homograft rejection. Surgery 55:412, 1964.
- Margules RM, Thibaut PM, Belzer FO, Kountz SL.
Long-term results of renal transplantation. Transplant Proc. 4:735, 1972.
- Markus BH, Hakala TR, Tzakis A, et al.
Kidney transplantation at Pittsburgh: experience and innovations. In: Terasaki PI (ed.), Clinical Transplants, 1987. Los Angeles, UCLA Tissue Typing Laboratory, 1987:141-154.
- Martino AN.
Rehabilitation: how can more dialysis and transplant patients be fully rehabilitated? Transplant Proc. 19(2 Suppl 2):107-110, 1987.
- Martyn S, Wright R, Clark L.
Required request for organ donation: moral, clinical and legal problems. Hastings Cent. Rpt. 18(2):27-34, 1988.
- Marumo F, Okubo M, Yokota K, et al.
A clinical study of renal transplant patients receiving triple-drug therapy--cyclosporin A, mizoribine, and prednisone. Transplant Proc. 20(1)(Suppl. 1):406-409, 1988.
- Mathew TH, d'Apice AJF, Kincaid-Smith PS.
Selection of patients and the integration between dialysis and transplantation, the quality of life of the patients. Second Edition. Drukker W, Parsons FM, Maher JF, eds. Replacement of Renal Function By Dialysis. Boston, MA: Martinus Nijhoff, 1983:820-829.

- Mathieu D, ed.
Organ Substitution Technology: Ethical, Legal, and Public Policy Issues.
 Boulder, CO: Westview Press, 1988.
- McCarthy CM.
 DRGs--five years later. N. Engl. J. Med. 318:1683-1686, 1988.
- McCormick MC, Shapiro S, Starfield BH.
 The regionalization of perinatal services. JAMA 253:799-804, 1985.
- McCullough J, Scott EP, Halagan N, McGlave P, Strand R.
 Effectiveness of a regional bone marrow donor program in providing donors for unrelated bone marrow transplantation. JAMA 259:3286-3289, 1988.
- McCusker J, Stoddard AM.
 Use of a surrogate for the Sickness Impact Profile. Med. Care 22: 789-795, 1984.
- McDonald JC.
 The National Organ Procurement and Transplantation Network. JAMA 259:725-726, 1988.
- McDowell I, Newell C.
Measuring Health: A Guide to Rating Scales and Questionnaires. New York: Oxford University Press, 1987.
- McEwen J.
 The Nottingham Health Profile: a measure of perceived health. In: Teeling-Smith, ed., Measuring the Social Benefits of Medicine. London: The Office of Health Economics, 1983:75-84.
- McGregor ChGA, Oyer PE, Shumway NE.
 Heart and heart-lung transplantation. Prog. Allergy. 38:346, 1986.
- McGregor M, Pelletier G.
 Planning of specialized health facilities: size vs. cost and effectiveness in heart surgery. N. Engl. J. Med. 299:179-181, 1987.
- McKevitt PM, Jones JF, Marion RR.
 The elderly on dialysis: physical and psychosocial functioning. Dial. Transplant 15:130-137, 1986.
- McKinlay JB.
 From "promising report" to "standard procedure": seven stages in the career of a medical innovation. Milbank Mem. Fund Q. 59:374-411, 1981.
- McMaster P, Haynes IG, Michael J, et al.
 Cyclosporine in cadaveric renal transplantation: a prospective randomized trial. Transplant Proc. 15(Suppl 1 and 2):2523-2527, 1983.

- Medawar PB.
Biological effects of heterologous antilymphocyte serum. In: Rapaport FT, Dausset J (eds.), Human Transplantation. New York: Grune and Stratton, 1968:501.
- Meinert CL.
Clinical Trials: Design, Conduct, and Analysis. New York: Oxford University Press, 1986.
- Melzer JS, Husing RM, Feduska NJ, et al.
The beneficial effect of pretransplant blood transfusions in cyclosporine-treated cadaver renal allograft recipients. Transplantation 43:61-64, 1987.
- Mendez R, Iwaki Y, Mendez R, Bogaard T, Self B, Terasaki PI.
Donor-specific blood transfusions: their immunologic effect and allograft outcome. Transplant Proc. 15:946-951, 1984.
- Merion RM, White DJG, Thiru S, Evans DB, Calne RY.
Cyclosporine: five years' experience in cadaveric renal transplantation. N. Engl. J. Med. 318:148-154, 1984.
- Merriken KJ, Overcast TD.
Governmental regulation of heart transplantation and the right to privacy. J. Contemporary Law 11:481-514, 1985.
- Metchnikoff E.
Etudes sur la resorption des cellules. Ann. Inst. Pasteur 13:737, 760, 1899.
- Miller JD, Jones PA.
The work of a regional head injury service. The Lancet 1(8438):1141-1144, 1985.
- Miller LW, Vitale-Noedel N, Pennington G, McBride L, Kanter KR.
Heart transplantation in patients over age fifty-five years. J. Heart Transplant 7:254-257, 1988.
- Modry DL, Stroeber S, Hoppe RT, et al.
Total lymphoid irradiation: experimental models and clinical application in organ transplantation. Heart Transplant 2:122-135, 1983.
- Mold JW, Stein HF.
The cascade effect in the clinical care of patients. N. Engl. J. Med. 315:320, 1986.
- Monaco AP.
Problems in transplantation -- ethics, education, expansion. Transplantation 43:1-4, 1987.

Monaco AP.

Biological immunosuppression: polyclonal antilymphocyte sera, monoclonal antibody, and donor-specific antigen. In: Cerilli GJ (ed.), Organ Transplantation and Replacement. New York: J.B. Lippincott Co., 1988:83-117.

Monaco A, Goldstein G, Barnes L.

Use of ORTHOCLONE OKT-3 monoclonal antibody to reverse acute renal allograft rejection unresponsive to treatment with conventional immunosuppressive regimens. Transplant Proc. 19(2)Suppl 1):28-31, 1987.

Moore FD.

How much cardiac transplantation -- and where? Heart Transplantation 1:254-256, 1982.

Moore FD.

The history of transplantation -- a lesson for our time. In: Cerilli GJ (ed.), Organ Transplantation and Replacement. New York: J.B. Lippincott Co., 1988:3-15.

Morris PJ.

Cyclosporin A. Transplantation 32:349-354, 1981.

Morris, PJ.

Renal transplantation - 1982. Transplant Proc. 15:1033-1038, 1983.

Morris PJ, French ME, Ting A, et al.

A controlled trial of cyclosporin A in renal transplantation. In: White DJG (ed.), Cyclosporin A. New York: Elsevier, 1982:355-364.

Morris PJ, French ME, Dunnill MS, Hunnisett AGW, Ting A, Thompson JF, Wood RFM.

A controlled trial of cyclosporine in renal transplantation with conversion to azathioprine and prednisolone after three months. Transplantation 36:273-276, 1983.

Morris PJ, Thompson JF, Ting A, Wood RFM.

Is pregraft blood transfusion beneficial in cyclosporine-treated renal transplant recipients? The Lancet 1(8368):98, 1984.

Morris PJ, Allen RD, Thompson JF, et al.

Cyclosporine conversion versus conventional immunosuppression: long-term follow-up and histological evaluation. The Lancet 1(8533):586-591, 1987.

Moses LE.

The evaluation of hospital death rates. JAMA 255:2801, 1986.

Moskop JC.

The moral limits to federal funding of kidney disease. Hastings Cent. Rpt. 17(2):11-15, 1987.

- Mourad G, Lygendre C, Argilles A, et al.
Triple drug immunosuppression (cyclosporine, azathioprine, and low-dose prednisolone): a safe and effective regimen in first cadaveric kidney transplantation. Transplant Proc. 19:3672-3673, 1987.
- Murray JE, Tilney NL, Wilson RE.
Renal transplantation: a twenty-five year experience. Ann. Surg. 184:565, 1976.
- Murray WR.
Hip problems associated with organ transplants. Clin. Orthop. 90:57, 1973.
- Myers BD.
Cyclosporine nephrotoxicity. Kidney Int. 30:964-974, 1986.
- Myers BD, Ross J, Newton L, et al.
Cyclosporine-associated chronic nephropathy. N. Engl. J. Med. 311:699-705, 1984.
- Nadel C, Clark JJ.
Psychosocial adjustment after renal retransplants. Gen. Hosp. Psychiatry 8:41-48, 1986.
- Nagi SZ.
An epidemiology of disability among adults in the United States. Milbank Memorial Fund Quarterly 54:439-467, 1976.
- Nagi SZ.
The concept and measurement of disability. In: Berkowitz ED, ed., Disability Policies and Government Programs. New York: Praeger, 1979: 1-15.
- Najarian JS.
Long-term results in renal transplants using cyclosporine. Transplantation and Immunology Letter 4(4):5-7, 1988.
- Najarian JS, Ferguson RM, Sutherland DER, et al.
Fractionated total lymphoid irradiation as preparative immunosuppression in high risk renal transplantation. Ann. Surg. 196:442, 1982.
- Najarian JS, Ferguson RM, Sutherland DER, et al.
A prospective trial of the efficacy of cyclosporine in renal transplantation at the University of Minnesota. Transplant Proc. 15:438-441, 1983.
- Najarian JS, Strand M, Fryd DS, et al.
Comparison of cyclosporine versus azathioprine-antilymphocyte globulin in renal transplantation. Transplant Proc. 15(Suppl. 1):2463-2468, 1983.

- Nakajima K, Sakamoto K, Ochiai T, Nagata M, Asano T, Isono K.
Prolongation of cardiac xenograft survival in rats treated with 15-Deoxyspergualin alone and in combination with FK506. Transplantation 45:1146-1148, 1988.
- National ESRD Patient Rehabilitation Task Force
Final Report of the National ESRD Patient Rehabilitation Task Force.
Transmitted by R. A. Gutman, chairperson, June 30, 1982.
- National News
Prudential decides to require transplants only at select hospitals.
Nephrology News and Issues, November 1988:12.
- National Task Force on Organ Transplantation.
Organ Transplantation: Issues and Recommendations. Rockville, MD:
Office of Organ Transplantation, Health Resources and Services
Administration, Department of Health and Human Services, 1986.
- Nazametz P.
Coverage decisions in a high-tech world. Business and Health 4(10):12-13, 1987.
- Neu S, Kjellstrand CM.
Stopping long-term dialysis: an empirical study of withdrawal of life-supporting treatment. N. Engl. J. Med. 314: 14-20, 1986.
- Newman H.
Exclusion of heart transplant procedures from Medicare coverage.
Federal Register 45(153):52296-52297, 1980.
- Newman HN.
Health Care Financing Administration, Medicare Program: solicitation of hospitals and medical centers to participate in a study of heart transplants. Federal Register 46:7072-7075, 1981.
- News.
Medico - legal issues associated with organ donation and transplantation: cadaver donors, living donors. PA Nurse 42(9):9, 14, 1987.
- Niblack GD, Richie RE.
Thoracic duct drainage-an overview. Heart Transplantation 2:197-203, 1983.
- Niessen GJCM, Marquet RL, Obertop H, et al.
Cyclosporine and blood transfusions in kidney transplantation. The Lancet 1(8372):339-340, 1984.
- Nossal GJV.
Current concepts: immunology: the basic components of the immune system. N. Engl. J. Med. 316:1320-1325, 1987.

Novick AC.

Uses of antilymphocyte globulin in renal transplantation. Urologic Clinics of North America 10(2):253-262, 1983.

Obituary.

Peter Brian Medawar. The Lancet 2(8564):923, 1987.

O'Brien BJ, Buxton MJ, Ferguson BA.

Measuring the effectiveness of heart transplant programmes: quality of life data and their relationship to survival analysis. J. Chron. Dis. 40 (Suppl 1):137s-153s, 1987.

Ochiai T, Sakamoto K, Nagata M, et al.

Studies on FK-506 in experimental organ transplantation. Transplant Proc. 20(1)(Suppl. 1):209-214, 1988.

Office of Technology Assessment.

Medical Technology and Costs of the Medicare Program. Washington, D.C.: U.S. Congress, Office of Technology Assessment, OTA-H-227, 1984.

Office of the Inspector General

The Access of Foreign Nationals to U.S. Cadaver Organs. Washington, D.C.: Office of Analysis and Inspection, Department of Health and Human Services, 1986.

Office of the Inspector General

The access of foreign nationals to U.S. cadaver organs: Part I. Nephrology News and Issues, 1(2):31-33, 1987.

Oka T, Nakane Y, Ohmori Y, et al.

Analysis of data on 170 consecutive patients transplanted with kidneys from living relatives. Japan J. Surg. 13:493-501, 1983.

Oka T, Omori Y, Aikawa I, et al.

Combination therapy of cyclosporine and azathioprine in living-related kidney transplant recipients compared with patients converted totally from cyclosporine to azathioprine. Transplant Proc. 20(3)(Suppl. 3):143-146, 1988.

O'Leary DS.

Quality assessment. JAMA 260:1760, 1988.

Olivari MT, Antolick A, Kaye MP, Jamieson SW, Ring WS.

Heart transplantation in elderly patients. J. Heart Transplant 7:258-264, 1988.

Opelz G.

HLA matching analysis of cyclosporine-treated cadaver kidneys transplanted in 1986. Transplant Proc. 19:3557-3558, 1987.

- Opelz G, Mickey MR, Terasaki PI.
Calculations on long-term graft and patient survival in human kidney transplantation. Transplant Proc. 9:27, 1977.
- Opelz G for the Collaborative Study Group.
Current relevance of the transfusion effect in renal transplantation. Transplant Proc. 17:1015-1022, 1985.
- Opelz G for the Collaborative Transplant Study.
Transfusions and cadaver kidney transplants. In: Terasaki PI (ed.), Clinical Transplants, 1987. Los Angeles, CA: UCLA Tissue Typing Laboratory, 1987:239-242.
- Ortho Multicenter Transplant Study Group.
A randomized clinical trial of OKT-3 monoclonal antibody for acute rejection of cadaveric renal transplants. N. Engl. J. Med. 313:337-342, 1985.
- Overcast TD, Evans RW, Bowen LE, Hoe MM, Livak CL.
Problems in the identification of potential organ donors. JAMA 251: 1559-1562, 1984.
- Paganini E.
The treatment of anemia in dialysis patients: present and future potentials of erythropoietin therapy. Nephrology News and Issues, October 1988:36.
- Paganini E.
Dr. Paganini editorializes on need for full reimbursement for r-HuEPO. Nephrology News and Issues, October, 1988:37.
- Parfrey PS, Vavasour HM, Gault MH.
A prospective study of health status in dialysis and transplant patients. Transplant Proc. 20(6):1231-1232, 1988.
- Patel CT.
Live renal donation: a viewpoint. Transplant Proc. 20(1)(Suppl 1):1068-1069, 1988.
- Paul LC, Henney FC, Lensen LM, et al.
Cyclosporine conversion in renal transplantation. The Lancet 1(8538):917, 1987.
- Penn I.
Malignancies associated with immunosuppression or cytotoxic therapy. Surgery 83:492, 1978.
- Penn I.
Tumor incidence in human allograft recipients. Transplant Proc. 11:1047, 1979.

- Penn I.
Problems of cancer in organ transplantation. Heart Transplantation 2:71-77, 1982.
- Penn I.
Renal transplantation in patients with preexisting malignancies. Transplant Proc. 15:1079-1082, 1983.
- Penn I.
Lymphomas complicating organ transplantation. Transplant Proc. 15(Suppl. 1 and 2):2790-2797, 1983.
- Penn I.
Cancer in immunosuppressed patients. Transplant Proc. 16:492-495, 1984.
- Penn I.
Cancers following cyclosporine therapy. Transplantation 43:32-35, 1987.
- Penn I.
Cancers after cyclosporine therapy. Transplant Proc. 20(Suppl 1):276-279, 1988.
- Penn I.
Development of new tumors after transplantation. In: Cerilli GJ (ed.), Organ Transplantation and Replacement. New York: JB Lippincott, Co., 1988:439-444.
- Perez LM, Schulman B, Davis F et al.
Organ donation in three American cities with large Latino and Black populations. Transplantation 46:553-557, 1988.
- Perloff LJ.
The role of blood transfusions in the age of cyclosporine. Transplant Proc. 18:29-33, 1986.
- Persijn GG.
HLA Matching and Blood Transfusion(s) in Renal Transplantation. The Hague, Netherlands: Drukkerij (J.H.), Pasmans (B.V.), 1985.
- Persijn GG, D'Amaro J, van Rood JJ.
Pretransplant blood transfusions and long-term renal allograft survival. The Lancet 2(8410):1043-1044, 1984.
- Persson H, Andersson C, Lundgren C, et al.
Improved renal graft function in triple-drug treatment with low-dose cyclosporine. Transplant Proc. 19:3586-3588, 1987.
- Peters TG, Reiter CG, Boswell RL.
Transmission of tuberculosis by kidney transplantation. Transplantation 38:514-516, 1984.

- Peters TG, Vaughn WK, Spees EK.
Multiple organ procurement and sharing: the SEOPF experience.
Transplant Proc. 20(5):829-832, 1988.
- Peterson OL, Bloom BS.
Regionalization of surgical services. Am. J. Public Health 73:179-183,
1983.
- Peterson PK, Rynasiewicz JJ, Simmons RL, et al.
Decreased incidence of overt cytomegalovirus disease in renal allograft
recipients after receiving cyclosporin A. Transplant Proc. 15:457-459,
1983.
- Pfeffermann R, Vidne B, Leapman S, Butt K, Kountz SL.
Urologic complications in renal primary and retransplantation.
Experience with 202 consecutive transplants. Am. J. Surg. 131:242,
1976.
- Pichlmayr R, Wonigeit K, Ringe B. et al.
Sandimmun (Ciclosporin) in Renal Transplantation: A Diagnostic and
Therapeutic Approach to Minimize Nephrotoxicity. Basle: Sandoz
Pharmaceuticals, 1985.
- Pierce WS.
Permanent heart substitution: better solutions lie ahead. JAMA 259:
891, 1988.
- Pocock SJ.
Clinical Trials: A Practical Approach. Somerset, NJ: Wiley, 1984.
- Pocock SJ, Hughes MD, Lee RJ.
Statistical problems in the reporting of clinical trials: a survey of three
medical journals. N. Engl. J. Med. 317:426-432, 1987.
- Pollard WE, Bobbitt RA, Bergner M, Martin DP, Gelson BS.
The Sickness Impact Profile: reliability of a health status measure.
Medical Care 14:146-155, 1976.
- Ponticelli C, Rivolta E, Tarantino A, et al.
Treatment of severe rejection of kidney transplants with Orthoclone
OKT-3. Clin. Transplantation 1:99-103, 1987.
- Powles RL, Morgenstern GR.
Cyclosporin-A to prevent graft-versus-host disease in man following
HLA/MLC matched allogeneic bone marrow transplantation. In: White
DJG (ed.), Cyclosporin A. New York: Elsevier Press, 1982:485-489.
- President's Commission for the Study of Ethical Problems in Medicine and
Biomedical and Behavioral Research.
Securing Access to Health Care. Washington, D.C.: U.S. Government
Printing Office, 1983.

- Pritchard J.
Tertiary oncology centers. The Lancet 1(8439):1220-1221, 1985.
- Prompt CA, Reis MM, Grillo FM, et al.
Transmission of AIDS virus at renal transplantation. The Lancet 2(8456): 672, 1985.
- Prottas JM.
In organ transplants, Americans first? Commentary. Hastings Center Report 16(5):23-24, 1986.
- Prowse SJ, Lafferty KJ.
The normal immune response. In: Cerilli GJ (ed.), Organ Transplantation and Replacement. Philadelphia: J.B. Lippincott Co., 1988:37-66.
- Ramos CP.
Cyclosporin A or azathioprine combined with prednisone in renal allotransplantation with conversion from cyclosporin A to azathioprine at four months. Proc. Eur. Dialysis Transplant Assoc. 22:571-575, 1985.
- Rao KV.
Renal transplantation: complications and results in the second decade. Transplant Proc. 19:3758-3759, 1987.
- Rapaport FT.
A rational approach to a common goal: the equitable distribution of organs for transplantation. JAMA 257:3118-3119, 1987.
- Read JL, Campbell PM.
Health care innovation: a progress report. Health Affairs 7(3):174-185, 1988.
- Reagan MD.
Health care rationing: what does it mean? N. Engl. J. Med. 319:1149-1151, 1988.
- Redbook, 1987
Drug Topics, Annual Pharmacist's Reference. Oradell, NJ: Medical Economics Co., 1987.
- Reiss JB, Burckhardt J, Hellinger F.
Cost and regulation of new medical technologies: heart transplants as a case study. In: McNeil BJ, Cravalho EG, eds., Critical Issues in Medical Technology. Boston, MA: Auburn House Publishing, 1982:399-417.
- Relman AS.
Assessment and accountability: the third revolution in medical care. N. Engl. J. Med. 319:1220-1222, 1988.

- Renlund DG, Bristow MR, Lybbert MR, O'Connell JB, Gay WA Jr.
Medicare-designated centers for cardiac transplantation. N. Engl. J. Med. 316:873-876, 1987.
- Revillard JP.
Depletion lymphocytaire par drainage du canol thoracique chez l'homme. Cah. Med. Lvon. 46:703, 1970.
- Rettig RA.
Implementing the End-Stage Renal Disease Program of Medicine. Rand Publication No. 2505-HCFA/HEW. Santa Monica, CA: Rand Corporation, 1980.
- Richardson YW.
The rehabilitation of dialysis and transplant patients. Transplant Proc. 19(2 Suppl 2):111-114, 1987.
- Ries PW.
Americans Assess Their Health: United States, 1978. Vital and Health Statistics. Series 10, No. 142. DHHS Publication No. (PHS) 83-1570. Washington DC: U.S. Government Printing Office, 1983.
- Roberts JP, Fryd DS, Ascher NL, et al.
Living-related kidneys continue to provide superior results over cadaveric kidneys in the cyclosporine era. Transplant Proc. 20(1)(Suppl 1):26-27, 1988.
- Roberts JC, Kjellstrand CM.
Choosing death. Withdrawal from chronic dialysis without medical reason. Acta Med. Scand. 223:181-186, 1988.
- Roberts NK, Cretin S.
The numbers game, or is small beautiful? N. Engl. J. Med. 304:666-667, 1981.
- Roberts R, Belitzky P, Cohen A, et al.
OKT-3 monoclonal antibody for severe acute renal allograft rejection. Clin. Transplantation 1:286-289, 1987.
- Robinson JC, Garnick DW, McPhee SJ.
Market and regulatory influences on the availability of coronary angioplasty and bypass surgery in U.S. Hospitals. N. Engl. J. Med. 317:85-90, 1987.
- Robitaille P, Lortie L, Mongeau J-G, Sinnassamy P.
Long-term follow-up of patients who underwent unilateral nephrectomy in childhood. The Lancet 1(8441):1297-1299, 1985.
- Rocher LL, Milford EL, Kirkman RL, et al.
Conversion from cyclosporine to azathioprine in renal allograft recipients. Transplantation 38:669, 1984.

- Rodenburg CJ, Kluin P, Maes A, Paul LC.
Malignant lymphoma confined to the heart, 13 years after a cadaver kidney transplant. N. Engl. J. Med. 313:122, 1985.
- Rodgers WL, Converse PE.
Measures of the perceived overall quality of life. Social Indicators Research 2:127-152, 1975.
- Rodin G, Voshart K., Cuttran D, et al.
Cadaveric renal transplant failure: the short-term sequelae. Int. J. Psychiatry 15:357-364, 1985.
- Rolles K, Merion R, Calne RY
Conversion problem -- azathioprine to cyclosporine. Transplant Proc. 15(4)(Suppl. 1):2878-2880, 1983.
- Roman J., Whiby MS, Atuk NO, Westervelt F.
Anemias with renal transplantation. JAMA 221:1283, 1972.
- Roos P, Lyttle D.
The centralization of operations and access to treatment: total hip replacement in Manitoba. Am. J. Public Health 75:130-133, 1987.
- Roper WL.
Medicare Program: Criteria for Medicare Coverage of Heart Transplants. Federal Register 52(65):10935-10951, 1987.
- Roper WL, Hackbarth GM.
HCFAs agenda for promoting high-quality care. Health Affairs 7(1):91-98, 1988.
- Roper WL, Winkeniverder W, Hackbarth GM, Krakauer H.
Effectiveness in health care: an initiative to evaluate and improve medical practice. N. Engl. J. Med. 319:1197-1202, 1988.
- Rosansky SJ.
Choosing therapy for end-stage renal disease. Am. Fam. Physician 28: 115-124, 1983.
- Rosenblatt R, Reinken J, Shoemack P.
Is obstetrics safe in small hospitals? Evidence from New Zealand's regionalized perinatal system. The Lancet 2(8452):429-432, 1985.
- Rosenthal R.
Meta-Analytic Procedures for Social Research. Beverly Hills, CA: Sage Publications, 1984.
- Ross JRY.
Centres of excellence. The Lancet 2(8552):219, 1987.

- Rubin RH.
Infection in the renal transplant patient. In: Rubin RH, Young LS (eds.), Clinical Approach to Infection in the Compromised Host. 2nd edition. New York: Plenum, in press.
- Rubin RH, Wolfson JS, Cosimi AB, et al.
Infection in the renal transplant patient. Am. J. Med. 70:405-411, 1981.
- Ruby G, Banta HD, Kesselman-Burns A.
Medicare coverage, Medicare costs, and medical technology. J. Health Politics, Policy, and Law 10(1):141-155, 1985.
- Rudicel S, Esdaile J.
Surgeons and trials. The Lancet 1(8496):1500-1501, 1986.
- Rudolf CS, Borker SR.
Regionalization. Issues in Intensive Care for High Risk Newborns and Their Families. Westport, CT: Praeger, 1987.
- Russell PS.
Centers for transplantation -- how many should we have? Surgery 100(5):867-876, 1986.
- Rynasiewicz JJ, Sutheland DER, Simmons RL, et al.
Cyclosporin A for the oliguric renal transplantation patient. The Lancet 1:276, 1981.
- Sackett DL, Haynes RB, Tugwell P.
Clinical Epidemiology: A Basic Science for Clinical Medicine. Boston: Little, Brown, 1985.
- Sacks HS, Berrier J, Reitman D, et al.
Meta-analysis of randomized controlled trials. N. Engl. J. Med. 316:450-455, 1987.
- Sacks HS, Berrier J, Reitman D, Ancona-Berk VA, Chalmers TC.
Meta-analysis. N. Engl. J. Med. 317:576-577, 1987.
- Sadeghi AM, Downing TP, Bieber CP, Reitz BA, Stinson EB, Shumway NE.
Heterotopic cardiac allograft in rats: Prolonged survival with low-dose preoperative and postoperative total lymphoid irradiation combined with low-dose cyclosporine. Heart Transplantation 2:209-211, 1983.
- Sagalowsky AI, Reisman MD, Davidson I, et al.
Late cyclosporine conversion carries risk of irreversible rejection. Transplant Proc. 20(3)(Suppl. 3):157-160, 1988.
- Salaman JR.
Steroids in organ transplantation. Heart Transplantation 2:118-121, 1983.

- Salaman JR.
Effects of steroids in combination with other pharmacologic immunosuppressive agents. J. Heart Transplant. 5:304-306, 1986.
- Salaman J.
Cyclosporine mono-drug therapy. Transplant Proc. 20(3)(Suppl.3):117-120, 1988.
- Salaman JR, Griffin PJA.
Immunosuppression with a combination of cyclosporine, azathioprine, and prednisolone may be unsafe. The Lancet 2(8463):1066-1067, 1985.
- Salaman JR, Griffin JA, Ross WB, Williams, JD.
A controlled trial of triple therapy in renal transplantation. Transplant Proc. 19:1935-1936, 1987.
- Salemans J, Hoitsma AJ, De Abreu RA, et al.
Pharmacokinetics of azathioprine and 6-mercaptopurine after oral administration of azathioprine. Clin. Transplantation 1:217-221, 1987.
- Salvatierra O, Jr.
The role of blood transfusions in transplantation. In: Cerilli GJ (ed.), Organ Transplantation and Replacement. New York: JB Lippincott, Co., 1988:151-161.
- Salvatierra O, Jr.
Optimal use of organs for transplantation. N. Engl. J. Med. 318:1329-1331, 1988.
- Salvatierra O, Feduska NJ, Vincenti F, et al.
Analysis of costs and outcomes of renal transplantation at one center. JAMA 241:1469-1473, 1979.
- Salvatierra O, Jr., Vincenti F, Amend WJC, Jr., Garovoy MR, Feduska NJ.
The enhancement of graft survival with pretransplant blood transfusions. Heart Transplantation 2:181-187, 1983.
- Salvatierra O, Jr., Vincenti F, Amend WJ, Jr., et al.
The role of blood transfusions in renal transplantation. Urologic Clinics in North America. 10(2):243-252, 1983.
- Salvatierra O, Jr., Vincenti W, Amend W, Jr., Garovoy MR, Iwaki Y, et al.
Four-year experience with donor-specific blood transfusions. Transplant Proc. 15:924-931, 1983.
- Salvatierra O, Melzer J, Garovoy M, et al.
A seven year experience with donor-specific blood transfusions: results and considerations for maximum efficacy. Transplantation 40:654-659, 1985.

- Salvatierra O, Melzer J, Vincenti, et al.
Donor-specific transfusions versus cyclosporine -- the DST story.
Transplant Proc. 19:160-166, 1987.
- Sampson D, Albert DJ.
Alternate day therapy with methylprednisolone after renal
transplantation. J. Urol. 109:345, 1973.
- Sampson D, Levin BS, Hoppe RT, et al.
Preliminary observations on the use of total lymphoid irradiation, rabbit
antithymocyte globulin, and low-dose prednisone in human cadaver renal
transplantation. Transplant Proc. 17:1299, 1985.
- Sanders RS, Dan BB.
Bless the seats and the children: the physician and the legislative
process. JAMA 252:2613-2614, 1984.
- Schaeffer LD.
Role of the HCFA in the regulation of new medical technologies. In:
McNeil BJ, Cravalho EG, eds., Critical Issues in Medical Technology.
Boston, MA: Auburn House Publishing, 1982.
- Schaffarzick RW.
Health care technology and quality of care. Am. Coll. Utilization Review
Physicians 2:84-89, 1987.
- Scher KS.
Importance of severity of illness in outcome assessment. N. Engl. J.
Med. 317:171, 1987.
- Schersten T, Byringer H, Karlberg I, Jonsson E.
Cost-effectiveness analysis of organ transplantation. Int. J. of
Technology Assessment in Health Care 2:545-552, 1986.
- Schniff M, Jr., McGuire EJ, Weiss RM, Lytton B.
Management of urinary fistulas after renal transplantation. Journal of
Urology 155:251-256, 1976.
- Schippers HM, Kalff MW.
Cost comparisons: haemodialysis and renal transplantation. Tissue
Antigens 7:86-90, 1976.
- Schroeder SA.
Outcome assessment 70 years later: are we ready? N. Engl. J. Med.
316:160-162, 1987.
- Schroder SA.
Outcome assessment. N. Engl. J. Med. 317:251-252, 1987.

- Schulak JA, Corry RJ.
Manipulation of the immune response: other methods. In: Cerilli GJ (ed.), Organ Transplantation and Replacement. New York: JB Lippincott, Co., 1988:137-150.
- Schwartz RS, Eisner A, Dameshek W.
The effect of 6-mercaptopurine on primary and secondary immune responses. J. Clin. Invest. 38:1394, 1959.
- Schwartz WB, Joskow PL.
Duplicated hospital facilities: how much can we save by consolidating them? N. Engl. J. Med. 303:1449-1457, 1980.
- Schweizer RT, Rovelli M, Roper L, Bartus SA.
A flexible immunosuppression protocol for organ transplantation using cyclosporine, azathioprine, and prednisone. Transplant Proc. 19:1944-1946, 1987.
- Scitovsky AA.
The economic impact of AIDS. Health Affairs 7(4):32-45, 1988.
- Scitovsky AA, Rice DP.
Estimates of the direct and indirect costs of acquired immunodeficiency syndrome in the United States, 1985, 1986, 1991. Public Health Rep. 102:5-17, 1987.
- Sell S.
Basic Immunology: Immune Mechanisms in Health and Disease. New York: Elsevier, 1987.
- Shapira Z, Yussim A, Shmueli D, et al.
Conversion from cyclosporin A to azathioprine: is it safe? Transplant Proc. 18:1261-1263, 1986.
- Shapiro SH, Louis TA (eds.)
Clinical Trials: Issues and Approaches. New York: Marcel Dekker, 1983.
- Shaw A.
QL revisited. Hastings Cent. Report 18(2):10-12, 1988.
- Sheil AGR, Hall BM, Tiller DJ, et al.
Preoperative administration of Cyclosporin A to cadaveric donor renal allograft recipients (preliminary report from a controlled clinical trial). In: White DJG (ed.), Cyclosporin A. New York: Elsevier, 1982:387-391.
- Sheil AGR, Hall BM, Tiller DJ, et al.
Australian trial of cyclosporine (CsA) in cadaveric donor renal transplantation. Transplant Proc. 15(Suppl. 1 and 2):2485-2489, 1983.

- Shield CF, Hughes JD, Lemon JA.
Prophylactic OKT-3 and cadaveric renal transplantation at a single center. Clin. Transplantation 2:190-193, 1988.
- Short PF, Monheit A, Beauregard K.
Uninsured Americans: a 1987 profile. Paper presented at the Annual Meetings of the American Public Health Association in Boston, MA. November 13-18, 1988.
- Showstack JA, Rosenfeld KE, Garnick DW, et al.
Association of volume with outcome of coronary artery bypass graft surgery. JAMA 257:785-789, 1987.
- Simmons RG, Anderson C, Kamstra L.
Comparison of quality of life of patients on continuous ambulatory peritoneal dialysis, hemodialysis, and after transplantation. Am. J. Kidney Dis. 4:253-255, 1984.
- Simmons RG, Klein-Marine S.
The regulation of high cost technology medicine: the case of dialysis and transplantation in the United Kingdom. J. Health Soc. Behavior 25:320-334, 1984.
- Simmons RG, Anderson CR, Kamstra LK, Ames NG.
Quality of life and alternate end-stage renal disease therapies. Transplant Proc. 17:1577-1578, 1985.
- Simmons RG, Klein SD, Simmons RL.
Gift of Life: The Effect of Organ Transplantation on Individual, Family, and Social Dynamics. New Brunswick, NJ: Transaction, 1987.
- Simmons RG, Abress L.
Quality of life and rehabilitation differences among alternate end-stage renal disease therapies. Transplant Proc. 20(1)(Suppl 1):379-380, 1988.
- Simmons RG, Abress L, Anderson CR.
Quality of life after kidney transplantation: A prospective, randomized comparison of cyclosporine and conventional immunosuppressive therapy. Transplantation 45:415-420, 1988.
- Simmons RG, Abress L, Anderson C.
Rehabilitation after kidney transplantation. In Cerilli GJ, ed., Organ Transplantation and Replacement. Philadelphia, PA: J.B. Lippincott Co., 1988:481-489.
- Simmons RG, Abress L.
Ethics in organ transplantation. In: Cerilli GJ, ed., Organ Transplantation and Replacement. Philadelphia, PA: J.B. lippincott Co., 1988:691-702.

- Simmons RL, Thompson EJ, Yunes EJ, et al.
115 patients with first cadaver kidney transplants followed two to seven and a half years. Am. J. Med. 62:234, 1977.
- Simpson JB.
State certificate-of-need programs: the current status. Am. J. Public Health. 75:1225-1229, 1985.
- Slapak M.
Triple and quadruple immunosuppressive therapy in organ transplantation. The Lancet 2(8565):958-960, 1987.
- Slapak M, Geoghegan T, Digard N, et al.
The use of low-dose cyclosporin A in combination with azathioprine and steroids in renal transplantation. Transplant Proc. 17:1222-1225, 1985.
- Slapak M, Digard N.
Safety of triple immunosuppressive treatment (cyclosporine, azathioprine and prednisolone). The Lancet 2(8468):1355, 1985.
- Slapak M, Shell T, Digard N, et al.
Triple and quadruple therapy after renal transplantation in patients from developing countries. Transplant Proc. 19:1922, 1987.
- Slavin S, Kaplan HS, Strober S.
Transplantation of allogeneic bone marrow without graft vs. host disease using total lymphoid irradiation (TLI). J. Exp. Med. 147:963, 1978.
- Slavin S, Kaplan HS, Strober S.
Transplantation of bone marrow in outbred dogs without graft vs. host disease using total lymphoid irradiation (TLI). Transplantation 27:139, 1979.
- Smith AY, Van Buren CT, Lewis RM, et al.
Factors affecting renal transplant outcome at the University of Texas at Houston. In: Terasaki PI (ed.), Clinical Transplants, 1987. Los Angeles: UCLA Tissue Typing Laboratory, 1987:155-166.
- Sollinger HW, Burlingham WJ, Sparks EMF, et al.
Donor-specific transfusions in unrelated and related HLA-mismatched donor-recipient combinations. Transplantation 38:612-615, 1984.
- Sollinger HW, Deierhoi M, Kalayoglu M, Belzer FO.
Sequential antilymphocyte globulin cyclosporine therapy in cadaver renal transplantation. Transplant Proc. 18(Suppl.1):16-18, 1986.
- Sommer BG, Henry ML, Ferguson RL.
Sequential conventional immunotherapy with maintenance cyclosporine following renal transplantation. Transplant Proc. 18(2)(Suppl 1):69-75, 1986.

- Sommer BG, Henry M, Ferguson RM.
Sequential antilymphoblast globulin and cyclosporine for renal transplantation. Transplantation 43:85-90, 1987.
- Sorian R, Firshein J.
Congress passes sweeping Medicare expansion. The Nation's Health 18(7):4, 1988.
- Spielberger M, Aigner F, Schmid T, et al.
Long-term results of cadaveric renal transplantation after conversion from cyclosporine to azathioprine: a controlled randomized trial. Transplant Proc. 20(3)(Suppl.3):169-170, 1988.
- Spital A, Spital M.
Donor's choice or Hobson's choice? Arch. Intern. Med. 145:1297-1301, 1985.
- Spital A, Spital M.
Kidney donation: reflections. Am. J. Nephrol. 7:49-54, 1987.
- Spital R, Spital M, Spital A.
The donor's decision in renal transplantation: a cost-benefit analysis. Am. J. Kidney Dis. 9:396-403, 1987.
- Squifflet JP, Pirson Y, Jamart J, et al.
Cyclosporine in cadaver renal transplantation at a center with good results using conventional treatment. Transplant Proc. 17:1212-1217, 1985.
- Standards Committee of the American Society of Transplant Surgeons.
Current results and expectations of renal transplantation. JAMA 246:1330-1331, 1981.
- Starfield B.
Measurement of outcome: a proposed scheme. Milbank Mem. Fund Quarterly 52:39-50, 1974.
- Starr P.
The Social Transformation of American Medicine. New York: Basic Books, 1982.
- Starzl TE.
Implied consent for cadaveric organ donation. JAMA 251:1592, 1984.
- Starzl TE, Halgrimson GC, Penn I, et al.
Cyclophosphamide and human organ transplantation. The Lancet 2:70, 1971.
- Starzl TE, Porter KA, Halgrimson CG, et al.
A decade follow-up in early cases of renal homotransplantation. Ann. Surg. 180:606, 1974.

- Starzl TE, Weil R, III, Iwatsuki S, et al.
The use of cyclosporin A and prednisone in cadaver kidney transplantation. Surg. Gynecol. Obstet. 151:17, 1980.
- Starzl TE, Klintmalm GBG, Iwatsuki S, et al.
Cyclosporin A and steroid therapy in 66 cadaver kidney recipients. Surg Gynecol Obstet. 153:486, 1981.
- Starzl TE, Hakala TR, Iwatsuki S, et al.
Cyclosporin A and steroid treatment in 104 cadaveric renal transplantation. In: White DJG (ed.), Cyclosporine A. New York: Elsevier, 1982:365-377.
- Starzl TE, Hakala TR, Rosenthal JT, et al.
Variable convalescence and therapy after cadaveric renal transplantation under cyclosporin A and steroids. Surg. Gynecol. Obstet. 154:819-825, 1982.
- Starzl TE, Hakala TR, Rosenthal JT, Iwatsuki S, Shaw BW, Jr.
The Colorado-Pittsburgh cadaveric renal transplantation study. Transplant Proc. 15(Suppl. 1 and 2):2459-2462, 1983.
- Starzl TE, Makowka L, Todo S.
FK-506: A potential breakthrough in immunosuppression. Transplant Proc. 19(5)(Suppl. 6):1-104, 1987.
- Starzl TE, Hakala TR, Tzakis A, et al.
A multifactorial system for equitable selection of cadaver kidney recipient. JAMA 257:3073-3075, 1987.
- Steed D.
The case for safety belt use. JAMA 260:3651, 1988.
- Stevenson LW, Donohue BC, Tillisch JH, Schulman B.
Urgent priority transplantation: When should it be done? J. Heart Transplant. 6:267-272, 1987.
- Stewart AL, Ware JE Jr, Brook RH, Davies-Avery A.
Conceptualization and Measurement of Health for Adults in the Health Insurance Study: Vol. II, Physical Health in Terms of Functioning. Publication No. R-1987/2-HEW. Santa Monica, CA: Rand, 1978.
- Stewart AL, Ware JE Jr, Brook RH.
Construction and Scoring of Aggregate Functional Status Indexes: Volume I. Publication No. R-2551-HHS. Santa Monica, CA: The Rand Corporation, 1981.
- Stewart AL, Ware JE Jr, Brook RH.
Construction and Scoring of Aggregate Functional Status Indexes: Volume II. Publication No. N-1706-HHS. Santa Monica, CA: The Rand Corporation, 1981.

- Stiller C and The Canadian Transplant Study Group.
The Canadian Trial of Cyclosporine: cyclosporine therapy compared to standard immunosuppression in renal transplants: an exploration of nephrotoxicity. Transplant Proc. 15(Suppl. 1 and 2):2479-2484, 1983.
- Stiller CR, St. C. Sinclair NR.
Immunological monitoring after transplantation. In: Morris PJ (ed.), Kidney Transplantation: Principles and Practice. London: Academic Press, 1979:251-265.
- Stiller CR, Laupacis A, Keown PA.
Clinical considerations in cyclosporine treatment in the human. Transplant Proc. 15:1886-1888, 1983.
- Stites DP, Stobo JD, Fudenberg HH, Wells JF (eds.)
Basic and Clinical Immunology. Los Altos, CA: Lange, 1984.
- St. J Collier D, Calne R, Thiru S, Kohno H, Levickis.
15-deoxyspergualin in experimental dog renal allografts. Transplant Proc. 10(1)(Suppl. 1):240-241, 1988.
- Stratta RJ, Armbrust MJ, Lorentzen DT, et al.
Cadaveric renal transplantation in the cyclosporine and OKT-3 eras: the University of Wisconsin--Madison experience. In: Terasaki PI (ed.), Clinical Transplants. 1987. Los Angeles: UCLA Tissue Typing Laboratory, 1987:183-193.
- Stratta RJ, Oh C-S, Sollinger HW, Pirsch JD, et al.
Kidney transplantation in the cyclosporine era. Transplantation 45:40-45, 1988.
- Strober S, Slavin S, Gottlieb M, et al.
Allograft tolerance after total lymphoid irradiation (TLI). Immunol. Rev. 46:87, 1979.
- Stuart FP, Hoag BW, Jones K, et al.
Conversion from cyclosporine to azathioprine therapy six months after kidney transplantation. Transplant Proc. 17:2681, 1985.
- Suthanthiran M, Garovoy MR.
Immunologic monitoring of the renal transplant recipient. Urologic Clinics of North America. 10:315-325, 1983.
- Sutherland DER, Ferguson RM, Simmons RL, et al.
Total lymphoid irradiation. Urologic Clinics of North America. 10(2):277-288, 1983.
- Sutherland DER, Ferguson RM, Rynasiewicz JJ, et al.
Total lymphoid irradiation versus cyclosporine for retransplantation in recipients at high risk to reject renal transplants. Transplant Proc. 15:460-464, 1983.

- Sutherland DER, Ferguson RM, Aeder MI, et al.
Total lymphoid irradiation and cyclosporine. Transplant Proc. 15(Suppl.1):2881-2888, 1983.
- Sutherland DER, Fryd DS, Strand MH.
Results of the Minnesota randomized prospective trial of cyclosporine versus azathioprine-antilymphocyte globulin for immunosuppression in renal allograft recipients. Am. J. Kid. Dis. 5:318-327, 1985.
- Swazey JP, Watkins JC, Fox RC.
Assessing the artificial heart: the clinical moratorium revisited. Int. J. of Technology Assessment in Health Care 2:387-410, 1986.
- Taggi F.
Safety helmet law in Italy. The Lancet 1(8578):182, 1988
- Tanaka H, Kuroda A, Marusawa H, et al.
Physiochemical properties of FK-506, a novel immunosuppressant isolated from *Streptomyces tsukubaensis*. Transplant Proc. 19(5)(Suppl. 6):11-16, 1988.
- Tanneberger S.
When must a new approach to treatment be introduced? The ethics of technology assessment. International Journal of Technology Assessment in Health Care 4:113-120, 1988.
- Tannock IF.
Treating the patient, not just the cancer. N. Engl. J. Med. 317:1534-1535, 1987.
- Tapson JS.
The risks of donor nephrectomy. Int. J. Artif. Organs 8:13-16, 1985.
- Task Force on Organ Transplantation.
Report to the Secretary and the Congress on Immunosuppressive Therapies. Rockville, MD: Health Resources and Services Administration, Department of Health and Human Services, 1985.
- Technology Evaluation and Coverage.
Criteria For Evaluating Institutions For Liver and Heart Transplants. Chicago, IL: Health Benefits Management Division, Blue Cross and Blue Shield, 1985.
- Tegzess A, Donker A, Meijer S, et al.
Improvement in renal function after conversion from cyclosporine to prednisone/azathioprine in renal transplant recipients. Transplant Proc. 17:1191, 1985.

- Tellis VA, Matas AJ, Veith FJ.
Vascular complications of transplantation. In: Cerilli GJ, ed., Organ Transplantation and Replacement Philadelphia, PA: J.B. Lippincott, 1988: 423-432.
- Terasaki PI (ed.).
Clinical Kidney Transplants, 1985. Los Angeles, CA: UCLA Tissue Typing Laboratory, 1985.
- Terasaki PI (ed.).
Clinical Transplants, 1986. Los Angeles, CA: UCLA Tissue Typing Laboratory, 1986.
- Terasaki PI (ed.).
Clinical Transplants, 1987. Los Angeles, CA: UCLA Tissue Typing Laboratory, 1987.
- Terasaki PI, (ed).
Clinical Transplants, 1988. Los Angeles, CA: UCLA Tissue Typing Laboratory, 1988.
- Terasaki PI, Perdue ST, Sasaki N, Mickey MR, Whitby L.
Improving success rates of kidney transplantation. JAMA 250:1065-1068, 1983.
- Thacker SB.
Meta-analysis. JAMA 259:1685-1689, 1988.
- Thiel G, Landmann J, Mihatsch MJ.
Optimal use of Sandimmune in renal transplantation: the Basle experience. In: Land W (ed.), Optimal Use of Sandimmune in Organ Transplantation. Berlin, Heidelberg: Springer, 1987:25-29.
- Thistlethwaite JR, Jr., Gaber AO, Haag BW, et al.
OKT-3 treatment of steroid-resistant renal allograft rejection. Transplantation 43:176-184, 1987.
- Thistlethwaite JR, Haag BW, Jones KW, Stuart JK, Stuart FP.
Elective conversion from cyclosporine to azathioprine in recipients with stable renal function 6 months after kidney transplantation. Human Immunol. 14:314-323, 1985.
- Thorpe KE.
Uncompensated care pools and care to the uninsured: lessons from the New York prospective hospital reimbursement methodology. Inquiry 25:344-353, 1988.
- Tilney NL.
Surgical considerations of renal transplantation. In: Tilney NL, Lazarus JM, eds., Surgical Care of the Patient with Renal Failure. Philadelphia, PA: W.B. Saunders, 1982:184-211.

- Tilney NL, Collins JJ Jr, Wilson RE.
Hemorrhagic pancreatitis. N. Engl. J. Med. 274:1051, 1966.
- Tilney NL, Murray JE.
The thoracic duct fistula as an adjunct to immunosuppression in human renal transplantation. Transplantation 5:1204, 1967.
- Tilney NL, Lazarus JM.
Cardiovascular disease in chronic renal failure. In: Tilney NL, Lazarus JM, eds., Surgical Care of the Patient with Renal Failure Philadelphia, PA: W.B. Saunders, 1982:98-112.
- Tilney NL, Lazarus JM.
Gastrointestinal complications of renal failure and transplantation. In: Tilney NL, Lazarus JM, eds., Surgical Care of the Patient with Renal Failure. Philadelphia, PA: W.B. Saunders, 1982:113-124.
- Tilney NL, Milford EL, Carpenter CB, et al.
Long-term results of cyclosporine treatment in renal transplantation. Transplant Proc. 18(2)(Suppl. 1):179-185, 1986.
- Tilney NL, Strom TB.
Chemical manipulation of the immune responses. In: Cerilli GJ (ed.), Organ Transplantation and Replacement. New York: JB Lippincott, Co., 1988:118-136.
- Todo S, Murase N, Ueda Y, et al.
Effect of FK-506 in experimental organ transplantation. Transplant Proc. 20(1)(Suppl. 1):215-219, 1988.
- Todo S, Murase N, Kahn D, et al.
Effect of 15-dioxyspergualin on experimental organ transplantation. Transplant Proc. 20(1)(Suppl. 1):233-236, 1988.
- Tokunaga K, Terasaki PI.
Kidney transplant regraft results improved by preoperative blood transfusions. The Lancet 2(8507):634-635, 1986.
- Toledo-Pereyra LH (ed.).
Immunology Essentials in Surgical Practice. Littleton, MA: PSG, 1988.
- Tolkoff-Rubin N, Rubin RH.
Infections in the organ transplant recipient. In: Cerilli GJ (ed.), Organ Transplantation and Replacement. Philadelphia, PA: JB Lippincott Co., 1988:445-461.
- Toussaint C, Kinnaert P, Vereerstraeten P.
Late mortality and morbidity at 5 and 18 years after kidney transplantation. Transplant Proc. 19:3760-3761, 1987.

- Toussaint C, Kinnaert P, Vereerstraeten P.
Late mortality and morbidity five to eighteen years after kidney transplantation. Transplantation 45:554-558, 1988.
- Towery OB, Perry S.
The scientific basis for coverage decisions by third-party payers. JAMA 245:59-61, 1981.
- Traeger J, Carraz M, Fries D, *et al.*
Studies of antilymphocyte globulins made from thoracic duct lymphocytes. Transplant Proc. 1:455, 1969.
- Uchida K, Orihara A, Yamada N, *et al.*
Two immunosuppressive drug regimens after renal transplantation: low-dosage of cyclosporine adjusted on the basis of high-performance liquid chromatography whole blood levels and prednisone. Transplant Proc. 20(1)(Suppl. 1):401-405, 1988.
- United States Renal Data System. USRDS Goldnotes. Washington, Urban Institute, October 28, 1988.
- United Network for Organ Sharing.
Bylaws. Richmond, VA: United Network for Organ Sharing, 1988.
- Valdeck BC, Goodwin EJ, Myers LP, Sinisi M.
Consumers and hospitals: the HCFA "death list." Health Affairs 7(1):122-125, 1988.
- Vanrenterghem Y, Waer M, Ang K., *et al.*
Cadaveric kidney transplantation in diabetics after total lymphoid irradiation (TLI). Transplant Proc. 16:636, 1984.
- Vanrenterghem Y, Waer M, Michielsen PA.
A controlled trial of one versus three months' cyclosporine and conversion to azathioprine in renal transplantation. Transplant Proc. 17:1162-1163, 1985.
- Vanrenterghem Y, Roels L, Lerut T, *et al.*
Long-term prognosis after cadaveric kidney transplantation. Transplant Proc. 19:3762-3764, 1987.
- van Rood JJ.
Pretransplant blood transfusion: Sure! But how and why? Transplant Proc. 15:915-916, 1983.
- Versluis DJ, Wenting GJ, Derkx FHM, *et al.*
Why and whom to convert from cyclosporine to conventional immunosuppression in kidney transplantation. Transplantation 44:387-389, 1987.

- Vladeck BC, Goodwin EJ, Myers LP, Sinisi M.
Consumer and hospitals: the HCFA "death list." Health Affairs 7(1):
122-125, 1988.
- Wachter KW.
Disturbed by meta-analysis? Science. 241:1407-1408, 1988.
- Waer M, Vanrenterghem Y, Roels L, et al.
Total lymphoid irradiation in renal cadaveric transplantation in diabetics.
The Lancet. 2(8468):1354, 1985.
- Wagner DP, Knaus WA, Draper EA.
Public release of hospital death rates. Health Affairs 5(2):148-153,
1986.
- Waksman BH, Arbouys S, Arnason BG.
The use of specific "lymphocytes" antisera to inhibit hypersensitive
reaction of the "delayed" type. J Exp Med. 114:997, 1961.
- Walden D, Wilensky GR, Kasper JA.
Changes in Health Insurance Status: Full-Year and Part-Year Coverage.
Data Preview 21. DHHS Pub No. (PHS) 85-3377. Rockville, MD: Public
Health Service, National Center for Health Services Research and Health
Care Technology Assessment, July, 1985.
- Waldman H.
Monoclonal antibodies for organ transplantation: prospects for the
future. Am J Kid Dis. 11:154-158, 1988.
- Walshe JM.
Centres of excellence. The Lancet 2(8555):397, 1987.
- Washer GF, Schroter GPJ, Starzl TE, Weil R, III.
Causes of death after kidney transplantation. JAMA 250:49-54, 1983.
- Weimar W, Baumgartner D, Hendriks GFJ, et al.
The prophylactic use of Orthoclone OKT-3 in kidney and heart
transplantation. Transplant Proc. 20(5)(Suppl 6):96-100, 1988.
- Weinstein M, Stason W.
Foundations of cost-effectiveness analysis for health and medical
practices. N. Engl. J. Med. 296: 716-721, 1977.
- Weinstein MC, Fineberg HV, Elstein AS, et al.
Clinical Decision Analysis. Philadelphia: W.B. Saunders Co., 1980.
- Weir MR, Kirkman RL, Strom TB, Tilney NL.
Chronic liver disease in recipients of long-term renal allografts: analysis
of morbidity and mortality. Kidney Intl. 28(Suppl.):839, 1985.

- Weiss NS.
Clinical Epidemiology: The Study of the Outcome of Illness. New York:
 Oxford University Press, 1986.
- Welch HG, Larson EB.
 Dealing with limited resources: the Oregon decision to curtail funding
 for organ transplantation. N Engl J Med 319:171-173, 1988.
- Welch HG, Larson EB.
 Oregon's decision to curtail funding for organ transplantation. N Engl J
 Med 319:1420, 1988.
- Wenk M, Bindschedler M, Costa M, et al.
 Pharmacokinetics of cyclosporine G in patients with renal failure.
Transplantation. 45:558-561, 1988.
- Wenger N, Mattson ME, Furburg C, Elinson J, eds.
The Assessment of Quality of Life in Cardiovascular Therapies. New
 York: Le Jacq Publishers, 1984.
- Wennberg JE, Bunker JP, Barnes BA.
 The need for assessing the outcome of common medical practices. Ann.
 Rev. Publ. Health 1:277-295, 1980.
- West JG, Williams MJ, Trunkey DP, Wolferth CC.
 Trauma systems: current status-future challenges. JAMA 259:3597-
 3600, 1988.
- White DG (ed.).
Cyclosporin-A: Proceedings of an International Conference on
 Cyclosporin-A. Amsterdam: Elsevier Biomedical Press, 1982.
- White DJG (ed.).
Cyclosporin A. New York: Elsevier Biomedical, 1982.
- White DJG.
 Immunosuppression. In: Calne RY (ed.), Liver Transplantation. New
 York: Grune and Stratton, 1983:201-209.
- White JK.
 A review of organ transplantation policy. Health Affairs 4(4):109-114,
 1985.
- Wilensky GR.
 Filling the gaps in health insurance. Health Affairs 7(3):133-149, 1988.
- Williams AF, Lund AK.
 Seat belt laws and occupant crash protection in the United States. Am
 J Publ Health 76:1438-1442, 1986.

- Williams AF, Preusser DF, Blomberg RD, Lund AK.
Seat belt use law enforcement and publicity in Elmira, New York: a reminder. Am J Publ Health 77:1450-1451, 1987.
- Williams AF, Wells JK.
The Tennessee Child Restraint Law in its third year. Am J Public Health 71:163-165, 1981.
- Wing AJ.
Why don't the British treat more patients with kidney failure? British Med J 287:1157-1158, 1983.
- Winde G., Dietl KH, Raidt H, et al.
Use of Orthoclone OKT3 as treatment of acute renal allograft rejection and as first-line therapy in kidney transplantation. Transplant Proc. 20 (5)(Suppl 6):87-89, 1988.
- Winearles CG, Pippard M, Downing MR, Oliver DO, Reid C, Cotes PM.
Effect of human erythropoietin derived from recombinant DNA on the anemia of patients maintained by chronic haemodialysis. The Lancet 2(8517):1175-1178, 1986.
- Winslow EBJ.
Cardiac rehabilitation. JAMA 258:1937-1938, 1987.
- Wolf FM.
Meta-Analysis: Quantitative Methods for Research Synthesis. Beverly Hills, CA: Sage Publications, 1986.
- Wood RFM.
Renal Transplantation: A Clinical Handbook. Eastbourne, England: Balliere Tindall, 1983.
- Wood R, Thompson J, Allen N, Ting A, Morris P.
The consequences of conversion from cyclosporine to azathioprine and prednisone in renal allograft recipients. Transplant Proc. 15(Suppl. 1):2862, 1983.
- Wood RFM, Thompson JF, Ting A, et al.
A randomized controlled trial of short-term cyclosporine therapy in renal transplantation (trial II). Transplant Proc. 17:1164-1165, 1985.
- Woodruff MFA, Forman B, Fraser KB.
The effects of antilymphocyte serum on circulatory antibody levels. J Immunol. 67:57, 1951.
- Woodruff MFA, Anderson NF.
Effect of lymphocyte depletion by thoracic duct fistula and administration of antilymphocytic serum on the survival of skin homograft in rats. Nature. 200:702, 1963.

- Woodruff MFA, Nolan B, Anderton JL et al.
Long survival after renal transplantation in man. Br J Surg. 63:85, 1976.
- Woods JE, et al.
Pancreatitis in renal allograft patients. Mayo Clin. Proc. 47:193, 1972.
- Woods JE, deWeerd JH, Johnson WJ, Anderson CF, Shorter RG.
Experience in human renal allotransplantation. Surg. Gynecol. Obstet 134:394, 1972.
- Wynn JJ, Pfaff WW, Patton PR, et al.
Late results of renal transplantation. Transplantation. 45:329-333, 1988.
- Xie T, Xu QJ.
Use of cyclosporine in cadaveric renal transplantation. Transplant Proc. 20(3)(Suppl. 3):99-101, 1988.
- Yamauchi J, Yamada O, Otsubo I, et al.
Prolongation of kidney transplant survival by donor-specific blood transfusion. Transplant Proc. 15:932-934, 1983.
- Younger SJ, Allen M, Bartlett E, et al.
Psychosocial and ethical implications of organ retrieval. N. Engl. J. Med. 313:321-324, 1985.
- Zan-Bar I, Slavin S, Strober S.
Induction and mechanism of tolerance to bovine serum albumin in mice given total lymphoid irradiation (TLI). J Immunol. 121:1400, 1978.
- Zeevi A, Duquesnoy R, Eiras G, et al.
In vitro effects of FK-506 in combination with other drugs. Transplant Proc. 20(1)(Suppl.1):220-222, 1988.
- Zuck D.
Centres of excellence. The Lancet 2(8555):397, 1987.
- Zuckowski CF, Calloway JM, Rhea WG.
Tolerance to a canine renal homograft induced by prednisolone. Surg Forum. 14:208, 1963.
- Zweibel NR.
Measuring quality of life near the end of life. JAMA 260:839-840, 1988.

APPENDIX A

STUDY ON IMMUNOSUPPRESSIVE APPROACHES TO THE TREATMENT
OF KIDNEY TRANSPLANT RECIPIENTS

AUTHORIZATION FOR REVIEW OF MEDICAL RECORDS
AND HOSPITAL BILLING INFORMATION

**STUDY ON IMMUNOSUPPRESSIVE APPROACHES TO THE
TREATMENT OF KIDNEY TRANSPLANT RECIPIENTS**

**AUTHORIZATION FOR REVIEW OF MEDICAL RECORDS
AND HOSPITAL BILLING INFORMATION**

Name: _____
(Please Print)

Transplant Center: _____

Date Transplant Performed: _____

This form authorizes a data abstractor for the Renal Transplantation Study being conducted by the Battelle Human Affairs Research Centers in Seattle, Washington, to study the hospital billing records and all or part of the medical records that apply to the treatment of my kidney disease, my kidney transplant, and any associated care as I have indicated below. (Please mark the appropriate responses.)

Authorization to Review Medical Records

_____ I give my permission to review and, if necessary, to make a copy of the *complete record* of the history of my kidney disease and treatment.

_____ I wish to restrict access to my medical records as indicated below:

Authorization to Review Hospital Billing Records

_____ I give my permission to review and, if necessary, to make a copy of the hospital billing records pertaining to my treatment for kidney disease, my transplant, and any associated care.

Signature: _____ Date: _____

This authorization must be signed by the recipient and will be valid for two years from date, unless otherwise directed by the recipient.

APPENDIX B

STUDY ON IMMUNOSUPPRESSIVE APPROACHES TO THE TREATMENT
OF KIDNEY TRANSPLANT RECIPIENTS

GENERAL CONSENT FORM

STUDY ON IMMUNOSUPPRESSIVE APPROACHES TO THE TREATMENT OF KIDNEY TRANSPLANT RECIPIENTS

GENERAL CONSENT FORM

You are being asked to participate in a study of kidney transplant recipients which is being conducted by the Battelle Human Affairs Research Centers in Seattle, Washington. In this study we are collecting information on kidney transplant recipients at five transplant centers across the United States. These centers include: (1) University of California, San Francisco; (2) Ohio State University; (3) University of Pittsburgh; (4) University of Texas, Houston; and (5) University of Wisconsin. All cadaveric transplant recipients 18 years of age or older who were transplanted for the first time at one of these five transplant centers from November 1, 1985 through October 31, 1986 are being asked to participate in the study.

If you agree to participate in the study, you will be asked to fill out a series of patient questionnaires. The first questionnaire will be mailed to you three months after your transplant operation. You will then receive follow-up questionnaires every three months throughout the data collection period. Data collection will end in April, 1987. These questionnaires will give us information about your health, your family and social life, your medical costs, your overall quality of life, and your experience with rehabilitation and social service agencies.

Your participation in this study is purely voluntary. You may refuse to fill out the questionnaires, or, if you decide to participate, you may leave any question or item unanswered.

While we would also like to obtain some information contained in the medical and billing records kept by your transplant center, your signature on this consent form gives us permission *only* to use the information you supply by your answers to the questionnaires; it does *not* give us permission to see your medical records or hospital billing information. We will review those items only if you give us permission to do so by signing the "Authorization for Review of Medical Records and Hospital Billing Information" form. If you give us permission to see your medical records, only information about your kidney transplant and treatment will be studied. In addition, you may restrict our access further by indicating on the authorization form that you wish us to examine the record of your treatment only between certain dates, or that you do not wish to disclose to us information in your medical records about any condition or subject matter.

All information that we receive based on your answers to the patient questionnaires, your medical records, and hospital billing records is kept *strictly confidential*. We will give no one, including the government or your doctors, the information you provide to us that would personally identify you. Your name will not appear on the questionnaires. Once the information has been collected, it will no longer be associated with your name.

There is very little risk in participating in the study, except perhaps possible fatigue or discomfort during completion of the surveys. If you decide not to participate in this study, or if you choose not to answer all of the questions, your treatment or any benefits you now receive as a transplant recipient will not be affected in any way.

If you have any questions about how we intend to use the information you provide, you may make a collect call to the Renal Transplant Study project director, Dr. Roger W. Evans, at (206) 525-3130. We hope that you will agree to participate in this important study; the results of this survey will provide a better understanding of the current status of kidney transplantation.

With the above assurances that my rights will be protected, I now give my consent to participate in this study.

Name: _____
(Please Print)

(Signature)

Date: _____

APPENDIX C

STUDY ON IMMUNOSUPPRESSIVE APPROACHES TO THE TREATMENT
OF KIDNEY TRANSPLANT RECIPIENTS

BASELINE MEDICAL RECORDS DATA ABSTRACTION FORM
CLINICAL DATA

RECIPIENT STUDY I.D. NUMBER _____

RECIPIENT MEDICARE HIC NUMBER _____

DATE THIS FORM WAS COMPLETED _____

1. What is the recipient's birthdate?

_____/_____/_____
MONTH DAY YEAR

2. Is the recipient male or female?

(CIRCLE ONE)

MALE 01

FEMALE 02

3. What is the recipient's race or ethnic identification?

(CIRCLE ONE)

BLACK 01

HISPANIC 02

NATIVE AMERICAN (AMERICAN INDIAN, ESKIMO, ALEUT) 03

WHITE 04

ASIAN OR PACIFIC ISLANDER 05

OTHER 06

DON'T KNOW -2

4. What was the recipient's height and dry body weight just prior to transplantation?

A. HEIGHT _____ FEET and _____ INCHES

B. WEIGHT _____ POUNDS

or

_____ KILOGRAMS

5. Which of the following best describes the recipient's body frame?

(CIRCLE ONE)

SMALL 01

MEDIUM 02

LARGE 03

6. What was the cause of the recipient's renal disease? *(Please record the 3-digit code corresponding to the recipient's renal condition—see Appendix.)*

7. When was the recipient's renal condition first diagnosed?

_____/_____/_____
MONTH DAY YEAR

8. When was the transplant procedure performed?

_____/_____/_____
MONTH DAY YEAR

9. Prior to the recipient's kidney transplant, which other treatment modalities has this patient been on since he or she began treatment for renal failure? *(Please provide the date when each treatment modality began and the date when each ended.)*

<u>TREATMENT MODALITY</u>	<u>DATE BEGAN</u>	<u>DATE ENDED</u>
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

10. Which, if any, of the following conditions did the recipient have at the time of transplant? (Also, for each condition that the recipient had, please rate the severity of the condition at the time of transplant.)

11 = Asymptomatic.

12 = Symptomatic, never treated with medication or surgery.

13 = Symptomatic, not treated at time of transplant, previously treated, but never hospitalized for this illness.

14 = Symptomatic, treated at time of transplant, but never hospitalized for this illness.

15 = Symptomatic, not treated at time of transplant, but previously hospitalized for this illness.

16 = Symptomatic, treated at time of transplant, previously hospitalized for this illness.

(CIRCLE YES OR
NO FOR EACH
CONDITION)

(IF YES, CIRCLE ONE NUMBER
TO INDICATE THE SEVERITY
OF THE CONDITION)

YES NO

A. CARDIOVASCULAR DISEASE

01 02 11 12 13 14 15 16

B. PULMONARY DISEASE

01 02 11 12 13 14 15 16

C. HEPATIC DISEASE

01 02 11 12 13 14 15 16

D. JUVENILE ONSET
DIABETES MELLITUS

01 02 11 12 13 14 15 16

E. ADULT ONSET
DIABETES MELLITUS
(INSULIN-DEPENDENT)

01 02 11 12 13 14 15 16

F. CANCER

01 02 11 12 13 14 15 16

11. Which, if any, of the following medications were prescribed for the recipient just prior to his/her transplant?

(CIRCLE YES OR NO FOR EACH ITEM)

		YES	NO
A.	ANTIHYPERTENSIVE	01	02
B.	ANTIARRHYTHMIC	01	02
C.	CARDIOTONIC	01	02
D.	ANTIINFLAMMATORY (STEROID)	01	02
E.	ANTIINFLAMMATORY (NON-STEROID)	01	02
F.	ANTICONVULSIVE	01	02

12. List all surgical procedures prior to the recipient's kidney transplant on the table below.

<u>DATE OF SURGERY</u> (Month/Day/Year)	<u>SURGICAL PROCEDURE</u>	<u>ICD CODE</u>

13. Please check the statement below that best describes the recipient's condition just prior to his/her transplant?

(CIRCLE ONE)

COMPLETE PHYSICAL AND/OR MENTAL DISABILITY:
PATIENT HOSPITALIZED OR ESSENTIALLY AT HOME 01 (GO TO Q.16)

SIGNIFICANT BUT NOT COMPLETE PHYSICAL
AND/OR MENTAL DISABILITY 02

SLIGHT OR NO PHYSICAL AND/OR MENTAL DISABILITY 03 (GO TO Q.15)

UNKNOWN 04 (GO TO Q.16)

14. How would you rate the degree of the recipient's disability just prior to his/her transplant?

(CIRCLE ONE)

PATIENT UNABLE TO WORK OR ATTEND SCHOOL 01 (GO TO Q.16)

PATIENT WORKED OR ATTENDED SCHOOL
PART-TIME (LESS THAN 50%) 02 (GO TO Q.16)

PATIENT WORKED OR ATTENDED SCHOOL
ESSENTIALLY FULL TIME 03 (GO TO Q.16)

UNKNOWN 04 (GO TO Q.16)

15. How would you rate the degree of the recipient's disability just prior to his/her transplant?

(CIRCLE ONE)

- PATIENT UNABLE TO WORK OR ATTEND SCHOOL 01
- PATIENT WORKED OR ATTENDED SCHOOL
PART-TIME (LESS THAN 50%) 02
- PATIENT WORKED OR ATTENDED SCHOOL
FULL-TIME BUT AT A LOWER LEVEL OF
PERFORMANCE THAN AT PRE-ILLNESS 03
- PATIENT WORKED OR ATTENDED SCHOOL
FULL-TIME AT PRE-ILLNESS LEVEL OF
PERFORMANCE 04
- PATIENT WAS PHYSICALLY AND MENTALLY
ABLE TO WORK OR ATTEND SCHOOL BUT
CHOSE NOT TO 05
- PATIENT WAS PHYSICALLY AND MENTALLY
ABLE TO WORK BUT WAS UNABLE TO FIND
WORK 06
- UNKNOWN 07

TRANSPLANT PROCEDURE

16. When was the recipient admitted to the hospital for the transplant procedure?

_____/_____/_____
MONTH DAY YEAR

17. Did the recipient receive pre-transplant blood transfusions?

(CIRCLE ONE)

YES 01

NO 02 (GO TO Q.19)

18. How many pre-transplant transfusions did the recipient receive?

_____ NUMBER OF TRANSFUSIONS

19. Did the recipient receive blood transfusions at the time of transplant?

(CIRCLE ONE)

YES 01

NO 02

20. While the recipient was hospitalized for the transplant, were any of the following procedures performed?

(CIRCLE YES OR NO FOR
EACH ITEM)

	YES	NO
A. SPLENECTOMY	01	02
B. THORACIC DUCT DRAINAGE	01	02
C. TOTAL LYMPHOID IRRADIATION	01	02

21. Was endarterectomy required for the donor renal artery?

(CIRCLE ONE)

YES..... 01

NO 02

22. Was endarterectomy required for the recipient?

(CIRCLE ONE)

YES 01

NO 02

23. How many arterial anastomoses were performed?

_____ NUMBER

24. What was the revascularization time?

_____ MINUTES

25. Was the anastomoses difficult?

(CIRCLE ONE)

YES 01

NO 02

26. Did the recipient require dialysis following the transplant procedure?

(CIRCLE ONE)

YES 01

NO 02 (GO TO Q.29)

27. How long did the recipient require dialysis following the transplant?

_____ DAYS

28. How many dialysis treatments were administered in this period following the transplant?

_____ NUMBER

29. How many days prior to the transplant did immunosuppression begin?

_____ DAYS

30. What initial immunosuppressants did the recipient receive? (Also, for each immunosuppressant that the recipient received, please record the initial dose.)

(CIRCLE YES OR NO
FOR EACH DRUG)

(IF YES, RECORD
INITIAL DOSE)

	YES	NO	
A. CYCLOSPORINE (ORAL)	01	02	_____ mg/kg/day
B. CYCLOSPORINE (PARENTERAL)	01	02	_____ mg/kg/day
C. PREDNISONE (OR OTHER STEROID)	01	02	_____ mg/kg/day
D. AZATHIOPRINE	01	02	_____ mg/kg/day
E. MINNESOTA ALG	01	02	_____ mg/kg/day
F. ATGAM	01	02	_____ mg/kg/day
G. MONOCLONAL ANTIBODIES (OKT-3)	01	02	_____ mg/kg/day
H. OTHER (SPECIFY) _____ _____	01	02	_____ mg/kg/day
I. OTHER (SPECIFY) _____ _____	01	02	_____ mg/kg/day
J. OTHER (SPECIFY) _____ _____	01	02	_____ mg/kg/day

31. Did the recipient begin cyclosporine therapy?

(CIRCLE ONE)

YES 01

NO 02 (GO TO Q.33)

32. When was cyclosporine therapy begun?

(CIRCLE ONE)

PRIOR TO THE DAY OF TRANSPLANT
(Record number of days prior _____) 01

DAY OF TRANSPLANT 02

AFTER THE DAY OF TRANSPLANT
(Record number of days after _____) 03

33. Please record the dose of the following immunosuppressive drugs that the recipient received on the day of discharge from the hospital following the transplant procedure.

- | | | |
|----------------------------------|-------|-----------|
| A. CYCLOSPORINE | _____ | mg/kg/day |
| B. PREDNISONE (OR OTHER STEROID) | _____ | mg/kg/day |
| C. AZATHIOPRINE | _____ | mg/kg/day |
| D. MONOCLONAL ANTIBODIES (OKT-3) | _____ | mg/kg/day |
| E. OTHER (SPECIFY) _____ | _____ | mg/kg/day |
| F. OTHER (SPECIFY) _____ | _____ | mg/kg/day |

34. When was the recipient discharged from the hospital following the transplant procedure?

_____/_____/_____
MONTH DAY YEAR

DONOR CHARACTERISTICS

35. What was the donor's age at the time of death?

_____ YEARS

36. Was the donor male or female?

(CIRCLE ONE)

MALE 01

FEMALE 02

37. What was the donor's race or ethnic identification?

(CIRCLE ONE)

BLACK 01

HISPANIC 02

NATIVE AMERICAN (AMERICAN INDIAN, ESKIMO, ALEUT) 03

WHITE 04

ASIAN OR PACIFIC ISLANDER 05

OTHER 06

DON'T KNOW -2

38. Which, if any, of the following conditions or diseases did the donor have at the time of death?

(CIRCLE YES OR NO FOR
EACH ITEM)

	YES	NO
A. HYPERTENSION	01	02
B. ARTERIOSCLEROSIS	01	02
C. DIABETES	01	02
D. MALIGNANCY	01	02
E. SEPSIS	01	02

39. Which, if any, of the following drugs were administered to the donor in the 24 hours prior to removal of the kidney?

(CIRCLE YES OR NO FOR EACH ITEM)

	YES	NO
A. VASOPRESSORS	01	02
B. DIURETICS	01	02
C. STEROIDS	01	02
D. ANTIBIOTICS	01	02

40. What was the donor's urine output in the last hour before kidney removal?

_____ m

41. Was the donor a multiple organ donor?

(CIRCLE ONE)

YES 01
 NO 02 (GO TO Q.43)
 DON'T KNOW 03 (GO TO Q.43)

42. What other organs or tissues were removed for transplantation?

(CIRCLE YES OR NO FOR EACH ITEM)

	YES	NO
A. HEART	01	02
B. LIVER	01	02
C. LUNGS	01	02
D. PANCREAS	01	02
E. CORNEAS	01	02
F. SKIN	01	02
G. BONES	01	02
H. OTHER (SPECIFY) _____	01	02

43. At the time of organ removal, was the donor kidney injured?

(CIRCLE ONE)

YES 01

NO 02

44. How many renal arteries were present in the donor kidney?

_____ NUMBER

45. What was the warm ischemia time?

_____ MINUTES

46. What was the cold time?

_____ HOURS and _____ MINUTES

47. What was the total pulsatile perfusion time?

_____ HOURS and _____ MINUTES

TRANSPLANT COSTS

48. Did the recipient experience a delay in receiving a kidney transplant because he or she was unable to afford immunosuppressive drugs?

(CIRCLE ONE)

YES	01
NO	02 (GO TO Q.50)
DON'T KNOW	03 (GO TO Q.50)

49. Which of the following drugs was the recipient unable to afford?

(CIRCLE ALL THAT APPLY)

A. CYCLOSPORINE	01
B. PREDNISONE (OR OTHER STEROID)	02
C. AZATHIOPRINE	03
D. OTHER (SPECIFY) _____	04
E. OTHER (SPECIFY) _____	05

50. Is the recipient receiving any assistance in paying for immunosuppressive drugs?

(CIRCLE ONE)

YES	01 (GO TO Q.52)
NO	02 (GO TO Q.52)

51. From what source(s) is the recipient receiving help in paying for immunosuppressive drugs?

(CIRCLE ALL THAT APPLY)

- | | |
|--|----|
| A. PRIVATE INSURANCE | 01 |
| B. HOSPITAL OR TRANSPLANT CENTER | 02 |
| C. MEDICARE | 03 |
| D. MEDICAID | 04 |
| E. STATE KIDNEY PROGRAM | 05 |
| F. SPECIAL PATIENT FUND | 06 |
| G. FEDERAL GRANT PROGRAM | 07 |
| H. FAMILY INCOME | 08 |
| I. OTHER (SPECIFY) _____ | 09 |

52. Charges for a patient's kidney transplant can be broken down into several categories including laboratory tests, diagnostic tests, pharmacy, medical, surgical, and central supplies, blood administration, operating room and anesthesia, room and board, professional fees, and so forth. Please provide a complete breakdown of charges for this patient's transplant operation according to the categories provided below. If your billing does not break out specific items that are listed, total them and place them under the "other" categories.

ITEM OR SERVICE	CHARGE
A. MEDICAL, SURGICAL, AND CENTRAL SUPPLIES	\$ _____
B. OPERATING ROOM AND ANESTHESIA (EXCLUDING PROFESSIONAL TIME)	\$ _____
C. PHARMACY	
C1. CYCLOSPORINE	\$ _____
C2. AZATHIOPRINE	\$ _____
C3. STEROIDS	\$ _____
C4. MONOCLONAL ANTIBODIES (OKT-3)	\$ _____
C5. OTHER IMMUNOSUPPRESSIVE DRUGS	\$ _____
C6. TAKE HOME OR DISCHARGE DRUGS	\$ _____
C7. I.V. SOLUTIONS	\$ _____
C8. ALL OTHER DRUGS	\$ _____
C9. TOTAL PHARMACY	\$ _____
D. LABORATORY TESTS	\$ _____
E. RADIOLOGY/NUCLEAR MEDICINE	\$ _____
F. OTHER DIAGNOSTIC TESTS	\$ _____
G. BLOOD ADMINISTRATION	\$ _____
H. OXYGEN AND GAS MIXTURES	\$ _____

	ITEM OR SERVICE	CHARGE
I.	PHYSICAL, VOCATIONAL, AND RESPIRATORY THERAPY	\$ _____
J.	DIALYSIS	\$ _____
K.	PROFESSIONAL FEES	
K.1.	ANESTHESIOLOGY	\$ _____
K.2.	NEPHROLOGY	\$ _____
K.3.	SURGERY	\$ _____
K.4.	RADIOLOGY	\$ _____
K.5.	PRIMARY CARE	\$ _____
K.6.	INTERNAL MEDICINE	\$ _____
K.7.	OTHER (SPECIFY) _____	\$ _____
K.8.	OTHER (SPECIFY) _____	\$ _____
K.9.	OTHER (SPECIFY) _____	\$ _____
K.10.	OTHER (SPECIFY) _____	\$ _____
K.11.	TOTAL PROFESSIONAL FEES	\$ _____
L.	ROOM AND BOARD	
L.1.	ICU	\$ _____
L.2.	GENERAL WARD	\$ _____
L.3.	TOTAL ROOM AND BOARD	\$ _____
M.	HISTOCOMPATIBILITY TESTING (RECIPIENT ONLY)	\$ _____
N.	DONOR KIDNEY ACQUISITION CHARGE	\$ _____
O.	OTHER (SPECIFY) _____ ...	\$ _____
P.	OTHER (SPECIFY) _____ ...	\$ _____
	GRAND TOTAL	\$ <u> </u>

APPENDIX

CAUSE OF RENAL DISEASE CODES

100	<u>GLOMERULONEPHRITIS (GN)</u>	300	<u>TUBULO INTERSTITIAL DISEASES</u>
110	<u>Membranous (GN)</u>	310	<u>Pyelonephritis</u>
120	<u>Membranoproliferative (GN)</u>	311	Acute
	(Mesangiocapillary GN)	312	Bacterial gram positive
	(Chronic hypocomplementemia GN)	313	Granulomatous
	(Lobular GN)	320	<u>Interstitial nephritis</u>
	(Mixed membranous prolif. GN)	321	Acute
121	Type I (Subendothelial deposits)	322	Chronic
122	Type II (Dense-deposit disease)	323	Drug induced
130	<u>IgA Nephropathy (Berger's Disease)</u>	324	Analgesic abuse nephropathy
	131 Cirrhotic GN	330	<u>Obstructive uropathy</u>
140	<u>Focal Glomerular Sclerosis (FGS)</u>	331	Congenital
	141 Focal-segmental GS (FSGS)	332	Acquired
	142 Focal-global sclerosis	333	Uretral reflux
150	<u>Post-infectious GN</u>	340	<u>Nephrolithiasis (Kidney stones)</u>
	(Acute bacterial/viral GN)	341	Gout (urate) nephropathy
	151 Post-streptococcal GN		
	152 Post-staphylococcal GN	400	<u>HEREDITARY-CONGENITAL DISORDERS</u>
	153 Post-viral GN	410	<u>Polycystic Kidney Disease</u>
160	<u>Focal Proliferative GN (Focal GN)</u>	420	<u>Hereditary nephritis</u>
	161 IgM nephropathy	421	Alport's Syndrome
	162 Heroin-induced GN	430	<u>Congenital hypoplasia</u>
170	<u>Diffuse Proliferative GN</u>	440	<u>Medullary Cystic disease</u>
	(Rapidly progressive GN)	450	<u>Congenital absence (aplasia)</u>
	(Acute GN)	460	<u>Congenital dysplasia</u>
	(Crescentic GN)	470	<u>Fabry's disease</u>
180	<u>Chronic GN</u>	480	<u>Cystinosis</u>
200	<u>VASCULAR DISORDERS</u>	500	<u>SYSTEMIC DISEASES</u>
210	<u>Arterionephrosclerosis</u>	510	<u>Diabetic nephropathy</u>
	211 Essential hypertension		Intercapillary glomerulosclerosis
	212 Secondary hypertension		(Kimmelsteil-Wilson disease)
	213 Malignant hypertension	520	<u>Coagulation disorder</u>
220	<u>Renovascular hypertension</u>	521	Hemolytic-uremic syndrome
	221 Renal artery stenosis	522	Thrombocytopenic purpura
	222 Renal artery thrombosis	530	<u>Amyloidosis</u>
230	<u>Hypertension of pregnancy</u>	540	<u>Multiple Myeloma</u>
	231 Eclampsia	541	k-light chain glomerulosclerosis
	232 Pre-eclampsia		
240	<u>Renal vein thrombosis</u>	600	<u>COLLAGEN-VASCULAR DISEASES</u>
250	<u>Cortical necrosis</u>	610	<u>Systemic lupus erythematosus (SLE)</u>
260	<u>Infarction</u>	611	Membranous lupus nephritis
		612	Mesangiopathic lupus nephritis
		613	Proliferative lupus nephritis

(Continued Next Page)

600 COLLAGEN-VASCULAR DISEASE (continued)

620 Vasculitis

621 Polyarteritis

622 Henoch-schonlein purpura

623 Wegener's granulomatosis

630 Anti-Glomerular Basement Membrane

(Anti-GBM disease)

631 Goodpasture's syndrome

640 Progressive systemic sclerosis

(Sclerodema)

650 Cryoglobulinemia

700 ACQUIRED RENAL DISEASE

710 Trauma

720 Toxins

730 Tumors

731 Renal cell carcinoma

800 UNDETERMINED

End-Stage Renal Disease

Chronic Renal Failure

APPENDIX D

STUDY ON IMMUNOSUPPRESSIVE APPROACHES TO THE TREATMENT
OF KIDNEY TRANSPLANT RECIPIENTS

FOLLOW-UP INFORMATION FORM
CLINICAL DATA



RECIPIENT STUDY I.D. NUMBER _____

RECIPIENT MEDICARE HIC NUMBER _____

DATE THIS FORM WAS COMPLETED _____

Follow-up data on the transplant recipient are to be collected for several periods following the transplant procedure. Follow-up data collection forms should be completed 3, 6, 9, 12, 15, and 18 months after the transplant. The beginning and ending dates for the various data collection periods are presented below.

NUMBER OF MONTHS POST-TRANSPLANT	FOLLOW-UP DATA COLLECTION PERIOD	
	BEGINNING DATE	ENDING DATE
3	date of discharge from hospital following transplant	3 months after transplant
6	3 months after transplant	6 months after transplant
9	6 months after transplant	9 months after transplant
12	9 months after transplant	12 months after transplant
15	12 months after transplant	15 months after transplant
18	15 months after transplant	18 months after transplant

1. When was the transplant procedure performed?

MONTH / DAY / YEAR

2. What was the ending date of the last follow-up data collection period? *(If this is the first follow-up period, record the date that the patient was discharged from the hospital following the transplant surgery.)*

MONTH / DAY / YEAR

3. What is the beginning date of this follow-up period?

MONTH / DAY / YEAR

4. What is the ending date of this follow-up period?

_____/_____/_____
MONTH DAY YEAR

5. Did the recipient's graft fail during this follow-up period?

(CIRCLE ONE)

YES 01

NO 02 (GO TO Q.8)

6. When did the graft fail (i.e., when did the recipient resume regular maintenance dialysis or receive another kidney transplant)?

_____/_____/_____
MONTH DAY YEAR

7. What was the primary cause of transplant failure? (Please record the 3-digit code corresponding to the cause of transplant failure—see Appendix 1).

_____-_____-_____

8. Did the recipient die during this follow-up period?

(CIRCLE ONE)

YES 01

NO 02 (GO TO Q.11)

9. When did the recipient die?

_____/_____/_____
MONTH DAY YEAR

10. What was the primary cause of death? (Please record the 2-digit code corresponding to the cause of death—see Appendix 2.)

_____-_____

PHARMACOLOGICAL DATA

11. Was cyclosporine administered at any time during this follow-up period?

(CIRCLE ONE)

YES 01

NO 02 (GO TO Q.19)

12. Was cyclosporine therapy begun during this follow-up period?

(CIRCLE ONE)

YES 01

NO 02 (GO TO Q.14)

13. When was cyclosporine begun?

_____/_____/_____
MONTH DAY YEAR

14. Was alternate day cyclosporine used during this follow-up period?

(CIRCLE ONE)

YES 01

NO 02

15. What was the maintenance dose of cyclosporine at the beginning of this follow-up period? (If the patient was not receiving alternate day cyclosporine, record the same dose for both the first and second days.)

A. FIRST DAY mg/kg/day

B. SECOND DAY mg/kg/day

16. What was the maintenance dose of cyclosporine at the end of the follow-up period? (If the patient was not receiving alternate day cyclosporine, record the same dose for both the first and second days.)

A. FIRST DAY mg/kg/day

B. SECOND DAY mg/kg/day

17. Was cyclosporine discontinued during this follow-up period?

(CIRCLE ONE)

YES 01

NO 02 (GO TO Q.19)

18. When was cyclosporine discontinued?

_____/_____/_____
MONTH DAY YEAR

19. Was azathioprine administered at any time during this follow-up period?

(CIRCLE ONE)

YES 01

NO 02 (GO TO Q.27)

20. Was azathioprine therapy begun during this follow-up period?

(CIRCLE ONE)

YES 01

NO 02 (GO TO Q.22)

21. When was azathioprine started?

_____/_____/_____
MONTH DAY YEAR

22. Was alternate day azathioprine used during this follow-up period?

(CIRCLE ONE)

YES 01

NO 02

23. What was the maintenance dose of azathioprine at the beginning of this follow-up period? (If the patient was not receiving alternate day azathioprine, record the same dose for both the first and second days.)

A. FIRST DAY mg/kg/day

B. SECOND DAY mg/kg/day

24. What was the maintenance dose of azathioprine at the end of this follow-up period? (If the patient was not receiving alternate day azathioprine, record the same dose for both the first and second days.)

A. FIRST DAY mg/kg/day

B. SECOND DAY mg/kg/day

25. Was azathioprine discontinued during this follow-up period?

(CIRCLE ONE)

YES 01

NO 02 (GO TO Q.27)

26. When was azathioprine discontinued?

_____/_____/_____
MONTH DAY YEAR

27. Were steroids administered at any time during this follow-up period?

(CIRCLE ONE)

YES 01

NO 02 (GO TO Q.27)

28. Were steroids begun during this follow-up period?

YES 01

NO 02 (GO TO Q.30)

29. When were steroids begun?

_____/_____/_____
MONTH DAY YEAR

30. Were alternate day steroids used during this follow-up period?

(CIRCLE ONE)

YES 01

NO 02

31. What was the maintenance dose of steroids at the beginning of this follow-up period? (If the patient was not receiving alternate day steroids, record the same dose for both the first and second days.)

A. FIRST DAY mg/kg/day

B. SECOND DAY mg/kg/day

32. What was the maintenance dose of steroids at the end of this follow-up period? (If the patient was not receiving alternate day steroids, record the same dose for both the first and second days.)

A. FIRST DAY mg/kg/day

B. SECOND DAY mg/kg/day

33. Were steroids discontinued during this follow-up period?

(CIRCLE ONE)

YES 01

NO 02 (GO TO Q.35)

34. When were steroids discontinued?

_____/_____/_____
MONTH DAY YEAR

35. What was the accumulated dose of steroids for treatment of rejection during this follow-up period? (Include doses tapering to maintenance level.)

A. ORAL mg

B. PARENTERAL mg

36. What is the total number of rejection episodes treated by steroids during this follow-up period?

_____ NUMBER

37. Was ALG/ATG administered at any time during this follow-up period (excluding conditioning regimen)?

(CIRCLE ONE)

YES 01

NO 02 (GO TO Q.40)

38. How long was ALG/ATG administered?

_____ DAYS

39. What was the total dose of ALG/ATG administered during this follow-up period?

_____ Mg

40. Were monoclonal antibodies (e.g., OKT-3) administered at any time during this follow-up period?

(CIRCLE ONE)

YES 01

NO 02 (GO TO Q.43)

41. How long were monoclonal antibodies administered?

_____ DAYS

42. What was the total dose of monoclonal antibodies administered during this follow-up period?

_____ Mg

LABORATORY AND OTHER TEST DATA

43. What was the recipient's serum creatinine during this follow-up period?

A. HIGHEST MEASURED DURING PERIOD _____ mg/dl

B. LOWEST MEASURED DURING PERIOD _____ mg/dl

C. MOST RECENT _____ mg/dl

44. For each EKG (electrocardiogram) performed during this follow-up period, record the date performed and indicate whether the test results were normal or abnormal. *(If no EKGs were performed, please place a check in the box provided below.)*

☐ NO EKGs WERE PERFORMED

<u>EKG</u>	<u>DATE TEST PERFORMED</u> <u>(MONTH, DAY, YEAR)</u>	<u>TEST RESULTS</u>	
		<u>NORMAL</u>	<u>ABNORMAL</u>
A.	____ / ____ / ____	01	02
B.	____ / ____ / ____	01	02
C.	____ / ____ / ____	01	02
D.	____ / ____ / ____	01	02
E.	____ / ____ / ____	01	02
F.	____ / ____ / ____	01	02

45. For each CHEST X-RAY performed during this follow-up period, record the date performed and indicate whether the test results were normal or abnormal. (If no chest X-rays were performed, please place a check in the box provided below.)

☐ NO CHEST X-RAYS WERE PERFORMED

CHEST X-RAY	DATE TEST PERFORMED (MONTH, DAY, YEAR)	TEST RESULTS	
		NORMAL	ABNORMAL
A.	____ / ____ / ____	01	02
B.	____ / ____ / ____	01	02
C.	____ / ____ / ____	01	02
D.	____ / ____ / ____	01	02
E.	____ / ____ / ____	01	02
F.	____ / ____ / ____	01	02

46. For each PELVIC X-RAY (e.g., Ultrasound, CAT scan, BUN) performed during this follow-up period, record the type of test, the date performed and indicate whether the test results were normal or abnormal. (If no pelvic X-rays were performed, please place a check in the box provided below.)

☐ NO PELVIC X-RAYS WERE PERFORMED

PELVIC X-RAY	TYPE OF TEST	DATE TEST PERFORMED (MONTH, DAY, YEAR)	TEST RESULTS	
			NORMAL	ABNORMAL
A.	_____	____ / ____ / ____	01	02
E.	_____	____ / ____ / ____	01	02
C.	_____	____ / ____ / ____	01	02
D.	_____	____ / ____ / ____	01	02
E.	_____	____ / ____ / ____	01	02
F.	_____	____ / ____ / ____	01	02

47. For each I.V.P. (intravenous pyelogram) performed during this follow-up period, record the date performed and indicate whether the test results were normal or abnormal. (If no I.V.P.s were performed, please place a check in the box provided below.)

☐ NO I.V.P.s WERE PERFORMED

<u>I.V.P.</u>	<u>DATE TEST PERFORMED</u> <u>(MONTH, DAY, YEAR)</u>	<u>TEST RESULTS</u>	
		<u>NORMAL</u>	<u>ABNORMAL</u>
A.	____ / ____ / ____	01	02
B.	____ / ____ / ____	01	02
C.	____ / ____ / ____	01	02
D.	____ / ____ / ____	01	02
E.	____ / ____ / ____	01	02
F.	____ / ____ / ____	01	02

48. For each RENOGRAM (i.e., RENOSCAN) performed during this follow-up period, record the date performed and indicate whether the test results were normal or abnormal. (If no Renograms were performed, please place a check in the box provided below.)

☐ NO RENOGRAMS WERE PERFORMED

<u>RENOGRAM</u>	<u>DATE TEST PERFORMED</u> <u>(MONTH, DAY, YEAR)</u>	<u>TEST RESULTS</u>	
		<u>NORMAL</u>	<u>ABNORMAL</u>
A.	____ / ____ / ____	01	02
B.	____ / ____ / ____	01	02
C.	____ / ____ / ____	01	02
D.	____ / ____ / ____	01	02
E.	____ / ____ / ____	01	02
F.	____ / ____ / ____	01	02

49. For each KIDNEY NEEDLE BIOPSY performed during this follow-up period, record the date performed and indicate whether the test results were normal or abnormal. (If no kidney needle biopsies were performed, please place a check in the box provided below.)

☐ NO KIDNEY NEEDLE BIOPSIES WERE PERFORMED

<u>KIDNEY NEEDLE BIOPSY</u>	<u>DATE TEST PERFORMED</u> <u>(MONTH, DAY, YEAR)</u>	<u>TEST RESULTS</u>	
		<u>NORMAL</u>	<u>ABNORMAL</u>
A.	____ / ____ / ____	01	02
B.	____ / ____ / ____	01	02
C.	____ / ____ / ____	01	02
D.	____ / ____ / ____	01	02
E.	____ / ____ / ____	01	02
F.	____ / ____ / ____	01	02

COMPLICATIONS

50. How many episodes of renal dysfunction did the recipient have during this follow-up period?

_____ NUMBER OF
EPISODES
(IF "0", GO TO Q.54)

51. How many of these episodes of renal dysfunction were treated:

A. With decreased cyclosporine only?

_____ NUMBER

B. With increased steroids only?

_____ NUMBER

C. With both decreased cyclosporine and
increased steroids?

_____ NUMBER

D. With ATG

_____ NUMBER

E. With monoclonal antibodies?

_____ NUMBER

F. With other (Specify)

_____ NUMBER

52. How many of these episodes of renal dysfunction were diagnosed as nephrotoxicity?

_____ NUMBER OF EPISODES

53. How many of these episodes of renal dysfunction required hospitalization?

_____ NUMBER OF EPISODES

54. Has the recipient experienced any of the following adverse reactions to cyclosporine? (If the recipient has not received cyclosporine, please place a check in the box provided below.)

☐ RECIPIENT DID NOT RECEIVE CYCLOSPORINE

(CIRCLE YES OR NO FOR EACH ITEM)

	YES	NO
A. TREMORS	01	02
B. PARESTHESIAS	01	02
C. MUSCLE WEAKNESS	01	02
D. TEMPERATURE SENSITIVITY	01	02
E. SEIZURES	01	02
F. HEPATIC TOXICITY	01	02
G. HIRSUTISM	01	02
H. LYMPHOMA	01	02
I. HYPERURICEMIA	01	02
J. HYPERKALEMIA	01	02
K. HYPERTENSION	01	02
L. GINGIVAL HYPERPLASIA	01	02

55. Using the 3-digit codes provided in Appendix 3, record all complications which were treated during this follow-up period.

RECORD DATE OF EACH COMPLICATION AND RESPECTIVE DISEASE CODE

(100) RENAL ALLOGRAFT:

Condition

a.	_____	Date	____/____/____	Code	_____
b.	_____	Date	____/____/____	Code	_____
c.	_____	Date	____/____/____	Code	_____
d.	_____	Date	____/____/____	Code	_____
e.	_____	Date	____/____/____	Code	_____
f.	_____	Date	____/____/____	Code	_____

(200) CARDIOVASCULAR COMPLICATIONS:

Condition

a.	_____	Date	____/____/____	Code	_____
b.	_____	Date	____/____/____	Code	_____
c.	_____	Date	____/____/____	Code	_____
d.	_____	Date	____/____/____	Code	_____
e.	_____	Date	____/____/____	Code	_____
f.	_____	Date	____/____/____	Code	_____

(300) INFECTION:

Condition

a.	_____	Date	____/____/____	Code	_____
b.	_____	Date	____/____/____	Code	_____
c.	_____	Date	____/____/____	Code	_____
d.	_____	Date	____/____/____	Code	_____
e.	_____	Date	____/____/____	Code	_____
f.	_____	Date	____/____/____	Code	_____

(400) IMMUNOLOGIC REJECTION:

Condition

a.	_____	Date	____/____/____	Code	_____
b.	_____	Date	____/____/____	Code	_____
c.	_____	Date	____/____/____	Code	_____
d.	_____	Date	____/____/____	Code	_____
e.	_____	Date	____/____/____	Code	_____
f.	_____	Date	____/____/____	Code	_____

(500) NEOPLASTIC DISEASE:

Condition

a. _____	Date	____/____/____	Code	_____
b. _____	Date	____/____/____	Code	_____
c. _____	Date	____/____/____	Code	_____
d. _____	Date	____/____/____	Code	_____
e. _____	Date	____/____/____	Code	_____
f. _____	Date	____/____/____	Code	_____

(600) UROLOGIC COMPLICATIONS:

Condition

a. _____	Date	____/____/____	Code	_____
b. _____	Date	____/____/____	Code	_____
c. _____	Date	____/____/____	Code	_____
d. _____	Date	____/____/____	Code	_____
e. _____	Date	____/____/____	Code	_____
f. _____	Date	____/____/____	Code	_____

(700) OTHER ORGAN SYSTEM COMPLICATIONS:

Condition

a. _____	Date	____/____/____	Code	_____
b. _____	Date	____/____/____	Code	_____
c. _____	Date	____/____/____	Code	_____
d. _____	Date	____/____/____	Code	_____
e. _____	Date	____/____/____	Code	_____
f. _____	Date	____/____/____	Code	_____

(800) IATROGENIC/SELF-INDUCED COMPLICATIONS:

Condition

a. _____	Date	____/____/____	Code	_____
b. _____	Date	____/____/____	Code	_____
c. _____	Date	____/____/____	Code	_____
d. _____	Date	____/____/____	Code	_____
e. _____	Date	____/____/____	Code	_____
f. _____	Date	____/____/____	Code	_____

HOSPITALIZATIONS

56. Was the recipient hospitalized on the beginning date of this follow-up period?

(CIRCLE ONE)

YES 01

NO 02

57. Was the recipient hospitalized on the ending date of this follow-up period?

(CIRCLE ONE)

YES 01

NO 02

58. How many times was the recipient discharged from the hospital during this follow-up period?

_____ NUMBER OF TIMES

59. For each time that the recipient was discharged from the hospital during this follow-up period, record the admission and discharge dates on the table below. Also, for each hospitalization, record the hospital costs as indicated by the table.

HOSPITALIZATION	ADMISSION DATE	DISCHARGE DATE	RECORD HOSPITAL COSTS IN:
#1	____/____/____	____/____/____	Question 60
#2	____/____/____	____/____/____	Question 61
#3	____/____/____	____/____/____	Question 62
#4	____/____/____	____/____/____	Question 63
#5	____/____/____	____/____/____	Question 64
#6	____/____/____	____/____/____	Question 65

60. Please provide a complete breakdown of the charges for the recipient's **FIRST** hospital stay according to the categories provided below. If your billing does not break out specific items that are listed, total them and place them under the "other" category.

ITEM OR SERVICE	CHARGE
A. MEDICAL, SURGICAL, AND CENTRAL SUPPLIES	\$
B. OPERATING ROOM AND ANESTHESIA (EXCLUDING PROFESSIONAL TIME)	\$
C. PHARMACY	
C.1. CYCLOSPORINE	\$
C.2. AZATHIOPRINE	\$
C.3. STEROIDS	\$
C.4. MONOCLONAL ANTIBODIES (OKT-3)	\$
C.5. OTHER IMMUNOSUPPRESSIVE DRUGS	\$
C.6. TAKE HOME OR DISCHARGE DRUGS	\$
C.7. I.V. SOLUTIONS	\$
C.8. ALL OTHER DRUGS	\$
C.9. TOTAL PHARMACY	\$
D. LABORATORY TESTS	\$
E. RADIOLOGY/NUCLEAR MEDICINE	\$
F. OTHER DIAGNOSTIC TESTS	\$
G. BLOOD ADMINISTRATION	\$
H. OXYGEN AND GAS MIXTURES	\$
I. PHYSICAL, VOCATIONAL, AND RESPIRATORY THERAPY	\$
J. DIALYSIS	\$

	ITEM OR SERVICE	CHARGE
K.	PROFESSIONAL FEES	
K.1.	ANESTHESIOLOGY	\$ _____
K.2.	NEPHROLOGY	\$ _____
K.3.	SURGERY	\$ _____
K.4.	RADIOLOGY	\$ _____
K.5.	PRIMARY CARE	\$ _____
K.6.	INTERNAL MEDICINE	\$ _____
K.7.	OTHER (SPECIFY) _____ ...	\$ _____
K.8.	OTHER (SPECIFY) _____ ...	\$ _____
K.9.	OTHER (SPECIFY) _____ ...	\$ _____
K.10.	OTHER (SPECIFY) _____ ...	\$ _____
K.11.	TOTAL PROFESSIONAL FEES	\$ _____
L.	ROOM AND BOARD	
L.1.	ICU	\$ _____
L.2.	GENERAL WARD	\$ _____
L.3.	TOTAL ROOM AND BOARD ..	\$ _____
M.	OTHER (SPECIFY) _____ ...	\$ _____
N.	OTHER (SPECIFY) _____ ...	\$ _____
	GRAND TOTAL	\$ _____

61. Please provide a complete breakdown of the charges for the recipient's **SECOND** hospital stay according to the categories provided below. If your billing does not break out specific items that are listed, total them and place them under the "other" category.

	ITEM OR SERVICE	CHARGE
A.	MEDICAL, SURGICAL, AND CENTRAL SUPPLIES	\$ _____
B.	OPERATING ROOM AND ANESTHESIA (EXCLUDING PROFESSIONAL TIME)	\$ _____
C.	PHARMACY	
C.1.	CYCLOSPORINE	\$ _____
C.2.	AZATHIOPRINE	\$ _____
C.3.	STEROIDS	\$ _____
C.4.	MONOCLONAL ANTIBODIES (OKT-3)	\$ _____
C.5.	OTHER IMMUNOSUPPRESSIVE DRUGS	\$ _____
C.6.	TAKE HOME OR DISCHARGE DRUGS	\$ _____
C.7.	I.V. SOLUTIONS	\$ _____
C.8.	ALL OTHER DRUGS	\$ _____
C.9.	TOTAL PHARMACY	\$ _____
D.	LABORATORY TESTS	\$ _____
E.	RADIOLOGY/NUCLEAR MEDICINE	\$ _____
F.	OTHER DIAGNOSTIC TESTS	\$ _____
G.	BLOOD ADMINISTRATION	\$ _____
H.	OXYGEN AND GAS MIXTURES	\$ _____
I.	PHYSICAL, VOCATIONAL, AND RESPIRATORY THERAPY	\$ _____
J.	DIALYSIS	\$ _____

	ITEM OR SERVICE	CHARGE
K.	PROFESSIONAL FEES	
K.1.	ANESTHESIOLOGY	\$ _____
K.2.	NEPHROLOGY	\$ _____
K.3.	SURGERY	\$ _____
K.4.	RADIOLOGY	\$ _____
K.5.	PRIMARY CARE	\$ _____
K.6.	INTERNAL MEDICINE	\$ _____
K.7.	OTHER (SPECIFY) _____ ...	\$ _____
K.8.	OTHER (SPECIFY) _____ ...	\$ _____
K.9.	OTHER (SPECIFY) _____ ...	\$ _____
K.10.	OTHER (SPECIFY) _____ ...	\$ _____
K.11.	TOTAL PROFESSIONAL FEES	\$ _____
L.	ROOM AND BOARD	
L.1.	ICU	\$ _____
L.2.	GENERAL WARD	\$ _____
L.3.	TOTAL ROOM AND BOARD	\$ _____
M.	OTHER (SPECIFY) _____ ...	\$ _____
N.	OTHER (SPECIFY) _____ ...	\$ _____
	GRAND TOTAL	\$ _____

62. Please provide a complete breakdown of the charges for the recipient's **THIRD** hospital stay according to the categories provided below. If your billing does not break out specific items that are listed, total them and place them under the "other" category.

ITEM OR SERVICE	CHARGE
A. MEDICAL, SURGICAL, AND CENTRAL SUPPLIES	\$
B. OPERATING ROOM AND ANESTHESIA (EXCLUDING PROFESSIONAL TIME)	\$
C. PHARMACY	
C.1. CYCLOSPORINE	\$
C.2. AZATHIOPRINE	\$
C.3. STEROIDS	\$
C.4. MONOCLONAL ANTIBODIES (OKT-3)	\$
C.5. OTHER IMMUNOSUPPRESSIVE DRUGS	\$
C.6. TAKE HOME OR DISCHARGE DRUGS	\$
C.7. I.V. SOLUTIONS	\$
C.8. ALL OTHER DRUGS	\$
C.9. TOTAL PHARMACY	\$
D. LABORATORY TESTS	\$
E. RADIOLOGY/NUCLEAR MEDICINE	\$
F. OTHER DIAGNOSTIC TESTS	\$
G. BLOOD ADMINISTRATION	\$
H. OXYGEN AND GAS MIXTURES	\$
I. PHYSICAL, VOCATIONAL, AND RESPIRATORY THERAPY	\$
J. DIALYSIS	\$

	ITEM OR SERVICE	CHARGE
K.	PROFESSIONAL FEES	
K.1.	ANESTHESIOLOGY	\$
K.2.	NEPHROLOGY	\$
K.3.	SURGERY	\$
K.4.	RADIOLOGY	\$
K.5.	PRIMARY CARE	\$
K.6.	INTERNAL MEDICINE	\$
K.7.	OTHER (SPECIFY)	\$
K.8.	OTHER (SPECIFY)	\$
K.9.	OTHER (SPECIFY)	\$
K.10.	OTHER (SPECIFY)	\$
K.11.	TOTAL PROFESSIONAL FEES	\$
L.	ROOM AND BOARD	
L.1.	ICU	\$
L.2.	GENERAL WARD	\$
L.3.	TOTAL ROOM AND BOARD	\$
M.	OTHER (SPECIFY)	\$
N.	OTHER (SPECIFY)	\$
	GRAND TOTAL	\$

63. Please provide a complete breakdown of the charges for the recipient's **FOURTH** hospital stay according to the categories provided below. If your billing does not break out specific items that are listed, total them and place them under the "other" category.

ITEM OR SERVICE	CHARGE
A. MEDICAL, SURGICAL, AND CENTRAL SUPPLIES	\$ _____
B. OPERATING ROOM AND ANESTHESIA (EXCLUDING PROFESSIONAL TIME)	\$ _____
C. PHARMACY	
C.1. CYCLOSPORINE	\$ _____
C.2. AZATHIOPRINE	\$ _____
C.3. STEROIDS	\$ _____
C.4. MONOCLONAL ANTIBODIES (OKT-3)	\$ _____
C.5. OTHER IMMUNOSUPPRESSIVE DRUGS	\$ _____
C.6. TAKE HOME OR DISCHARGE DRUGS	\$ _____
C.7. I.V. SOLUTIONS	\$ _____
C.8. ALL OTHER DRUGS	\$ _____
C.9. TOTAL PHARMACY	\$ _____
D. LABORATORY TESTS	\$ _____
E. RADIOLOGY/NUCLEAR MEDICINE	\$ _____
F. OTHER DIAGNOSTIC TESTS	\$ _____
G. BLOOD ADMINISTRATION	\$ _____
H. OXYGEN AND GAS MIXTURES	\$ _____
I. PHYSICAL, VOCATIONAL, AND RESPIRATORY THERAPY	\$ _____
J. DIALYSIS	\$ _____

	ITEM OR SERVICE	CHARGE
K.	PROFESSIONAL FEES	
K.1.	ANESTHESIOLOGY	\$ _____
K.2.	NEPHROLOGY	\$ _____
K.3.	SURGERY	\$ _____
K.4.	RADIOLOGY	\$ _____
K.5.	PRIMARY CARE	\$ _____
K.6.	INTERNAL MEDICINE	\$ _____
K.7.	OTHER (SPECIFY) _____ ...	\$ _____
K.8.	OTHER (SPECIFY) _____ ...	\$ _____
K.9.	OTHER (SPECIFY) _____ ...	\$ _____
K.10.	OTHER (SPECIFY) _____ ...	\$ _____
K.11.	TOTAL PROFESSIONAL FEES	\$ _____
L.	ROOM AND BOARD	
L.1.	ICU	\$ _____
L.2.	GENERAL WARD	\$ _____
L.3.	TOTAL ROOM AND BOARD	\$ _____
M.	OTHER (SPECIFY) _____ ...	\$ _____
N.	OTHER (SPECIFY) _____ ...	\$ _____
	GRAND TOTAL	\$ _____

64. Please provide a complete breakdown of the charges for the recipient's **FIFTH** hospital stay according to the categories provided below. If your billing does not break out specific items that are listed, total them and place them under the "other" category.

	ITEM OR SERVICE	CHARGE
A.	MEDICAL, SURGICAL, AND CENTRAL SUPPLIES	\$ _____
B.	OPERATING ROOM AND ANESTHESIA (EXCLUDING PROFESSIONAL TIME)	\$ _____
C.	PHARMACY	
C.1.	CYCLOSPORINE	\$ _____
C.2.	AZATHIOPRINE	\$ _____
C.3.	STEROIDS	\$ _____
C.4.	MONOCLONAL ANTIBODIES (OKT-3)	\$ _____
C.5.	OTHER IMMUNOSUPPRESSIVE DRUGS	\$ _____
C.6.	TAKE HOME OR DISCHARGE DRUGS	\$ _____
C.7.	I.V. SOLUTIONS	\$ _____
C.8.	ALL OTHER DRUGS	\$ _____
C.9.	TOTAL PHARMACY	\$ _____
D.	LABORATORY TESTS	\$ _____
E.	RADIOLOGY/NUCLEAR MEDICINE	\$ _____
F.	OTHER DIAGNOSTIC TESTS	\$ _____
G.	BLOOD ADMINISTRATION	\$ _____
H.	OXYGEN AND GAS MIXTURES	\$ _____
I.	PHYSICAL, VOCATIONAL, AND RESPIRATORY THERAPY	\$ _____
J.	DIALYSIS	\$ _____

	ITEM OR SERVICE	CHARGE
K.	PROFESSIONAL FEES	
K.1.	ANESTHESIOLOGY	\$ _____
K.2.	NEPHROLOGY	\$ _____
K.3.	SURGERY	\$ _____
K.4.	RADIOLOGY	\$ _____
K.5.	PRIMARY CARE	\$ _____
K.6.	INTERNAL MEDICINE	\$ _____
K.7.	OTHER (SPECIFY) _____ ...	\$ _____
K.8.	OTHER (SPECIFY) _____ ...	\$ _____
K.9.	OTHER (SPECIFY) _____ ...	\$ _____
K.10.	OTHER (SPECIFY) _____ ...	\$ _____
K.11.	TOTAL PROFESSIONAL FEES	\$ _____
L.	ROOM AND BOARD	
L.1.	ICU	\$ _____
L.2.	GENERAL WARD	\$ _____
L.3.	TOTAL ROOM AND BOARD	\$ _____
M.	OTHER (SPECIFY) _____ ...	\$ _____
N.	OTHER (SPECIFY) _____ ...	\$ _____
	GRAND TOTAL	\$ _____

65. Please provide a complete breakdown of the charges for the recipient's **SIXTH** hospital stay according to the categories provided below. If your billing does not break out specific items that are listed, total them and place them under the "other" category.

ITEM OR SERVICE		CHARGE
A.	MEDICAL, SURGICAL, AND CENTRAL SUPPLIES	\$ _____
B.	OPERATING ROOM AND ANESTHESIA (EXCLUDING PROFESSIONAL TIME)	\$ _____
C.	PHARMACY	
C.1.	CYCLOSPORINE	\$ _____
C.2.	AZATHIOPRINE	\$ _____
C.3.	STEROIDS	\$ _____
C.4.	MONOCLONAL ANTIBODIES (OKT-3)	\$ _____
C.5.	OTHER IMMUNOSUPPRESSIVE DRUGS	\$ _____
C.6.	TAKE HOME OR DISCHARGE DRUGS	\$ _____
C.7.	I.V. SOLUTIONS	\$ _____
C.8.	ALL OTHER DRUGS	\$ _____
C.9.	TOTAL PHARMACY	\$ _____
D.	LABORATORY TESTS	\$ _____
E.	RADIOLOGY/NUCLEAR MEDICINE	\$ _____
F.	OTHER DIAGNOSTIC TESTS	\$ _____
G.	BLOOD ADMINISTRATION	\$ _____
H.	OXYGEN AND GAS MIXTURES	\$ _____
I.	PHYSICAL, VOCATIONAL, AND RESPIRATORY THERAPY	\$ _____
J.	DIALYSIS	\$ _____

	ITEM OR SERVICE	CHARGE
K.	PROFESSIONAL FEES	
K.1.	ANESTHESIOLOGY	\$
K.2.	NEPHROLOGY	\$
K.3.	SURGERY	\$
K.4.	RADIOLOGY	\$
K.5.	PRIMARY CARE	\$
K.6.	INTERNAL MEDICINE	\$
K.7.	OTHER (SPECIFY)	\$
K.8.	OTHER (SPECIFY)	\$
K.9.	OTHER (SPECIFY)	\$
K.10.	OTHER (SPECIFY)	\$
K.11.	TOTAL PROFESSIONAL FEES	\$
L.	ROOM AND BOARD	
L.1.	ICU	\$
L.2.	GENERAL WARD	\$
L.3.	TOTAL ROOM AND BOARD	\$
M.	OTHER (SPECIFY)	\$
N.	OTHER (SPECIFY)	\$
	GRAND TOTAL	\$

APPENDIX 1

CAUSE OF RENAL FAILURE CODES

CODE	CAUSE
010	Acute Rejection
020	Chronic Rejection
030	Hyperacute Rejection (Biopsy-Proved)
040	Accelerated Humoral Rejection
050	Primary Non-Function
060	Recurrence of Original Disease (Biopsy-Proved)
070	Papillary Necrosis
080	Parenchymal Abscess
090	Parenchymal Hemorrhage
100	Local Wound Infection
110	Arterial Hemorrhage
120	Venous Hemorrhage
130	Renal Vein Thrombosis
140	Renal Artery Thrombosis
150	Renal Artery Stenosis
160	Inadequate Graft Vasculature
170	Bladder Leak
180	Ureteral Leak
190	Ureteral Obstruction
200	Renal Pelvic or Cortical Leak
210	Stable Renal Function But Withdrawal of Maintenance Immunosuppression Because of:
211	Infection
212	Gastro-Intestinal Hemorrhage
213	Visceral Perforation
214	Malignancy
215	Skeletal Complications
216	Steroid Psychosis
217	Other. Specify: _____
220	Poor Patient Compliance With Maintenance Immunosuppression
230	Other



APPENDIX 2

CAUSE OF DEATH

CODE	CAUSE
01	PERICARDITIS (Including cardiac tamponade)
02	MYOCARDIAL INFARCTION, ACUTE CARDIAC
03	CARDIAC (Other than 01 or 02)
04	CEREBROVASCULAR (Including spontaneous subdural hematoma)
05	EMBOLISM, AIR
06	EMBOLISM, PULMONARY
07	GI HEMORRHAGE
08	VASCULAR ACCESS HEMORRHAGE
09	HEMORRHAGE (Other than 04, 07, or 08)
10	PULMONARY INFECTION
11	SEPTICEMIA
12	VIRAL HEPATITIS
13	INFECTION (Other than 10, 11, or 12)
14	HYPERKALEMIA
15	PANCREATITIS
16	MALIGNANCY
17	WITHDRAWAL FROM DIALYSIS
18	SUICIDE
19	ACCIDENTAL DEATH, TREATMENT RELATED (Other than 05)
20	ACCIDENTAL DEATH NOT TREATMENT RELATED
21	UNKNOWN CAUSE
22	OTHER (SPECIFY) _____

APPENDIX 3
COMPLICATIONS



100	<u>RENAL ALLOGRAFT</u>	240	<u>Peripheral vascular</u>
110	<u>Anastomotic complications</u>	241	Arterial embolus
111	Arterial hemorrhage	242	Arterial thrombus
112	Arterial thrombosis	243	Arterial hemorrhage
113	Arterial aneurysm	244	Vascular access hemorrhage
114	Arterial stenosis	245	Vascular access thrombosis
115	Venous hemorrhage	246	Thrombophlebitis
116	Venous thrombosis	247	Peripheral vascular insufficiency
117	Venous stenosis	250	<u>Congestive Heart Failure</u>
118	Hematoma requiring re-operation	260	<u>Hypertension</u>
119	Vascular technical failure	261	Renal vascular hypertension
120	<u>Ischemic-metabolic complications</u>	262	Malignant hypertension
121	Acute tubular necrosis (ATN)	300	<u>INFECTION</u>
122	Acute cortical necrosis	310	<u>Wound Infection</u>
123	Primary non-function, unknown etiology	311	Bacterial-gram negative
130	<u>Infections</u>	312	Bacterial-gram positive
131	Superficial wound infections	313	Bacterial-unknown
132	Perinephric infections	314	Fungal
133	Wound related sepsis	315	Viral
140	<u>Allograft rupture</u>	316	Mycobacterial
150	<u>Incisional hernia</u>	317	Protozoan/metazoan/parasitic
160	<u>Renal abscess</u>	318	Unknown agent
170	<u>Renal parenchymal hemorrhage</u>	319	Other agent
180	<u>Renal pelvic or cortical leak</u>	320	<u>Urinary tract infection</u>
200	<u>CARDIOVASCULAR COMPLICATIONS</u>	321	Bacterial-gram negative
210	<u>Cardiac complications</u>	322	Bacterial-gram positive
211	Post-operative hypertension	323	Bacterial-unknown
212	Arrhythmia	324	Fungal
213	Cardiac arrest	325	Viral
214	Myocardial infarction	326	Mycobacterial
215	Endocarditis	327	Protozoan/metazoan/parasitic
216	Pericarditis	328	Unknown agent
217	Digitalis toxicity	329	Other agent
218	Angina pectoris	330	<u>Pulmonary</u>
219	Pericardial effusion	331	Bacterial-gram negative
220	<u>Pulmonary Circulation</u>	332	Bacterial-gram positive
221	Pulmonary embolus	333	Bacterial-unknown
222	Hemoptysis	334	Fungal
223	Pulmonary edema	335	Viral
224	Pulmonary hypertension	336	Mycobacterial
230	<u>Cerebral Circulation</u>	337	Protozoan/metazoan/parasitic
231	Carotid insufficiency	338	Unknown agent
232	Cerebral aneurysm	339	Other agent
233	Cerebral thrombosis	340	<u>Septicemia</u>
234	Cerebral embolism	341	Bacterial-gram negative
235	Cerebral hemorrhage	342	Bacterial-gram positive
236	Subarachnoid hemorrhage	343	Bacterial-unknown
237	Post-operative coma	344	Fungal
238	Cerebrovascular accident (stroke)	345	Viral
		346	Mycobacterial
		347	Protozoan/metazoan/parasitic
		348	Unknown agent
		349	Other agent

350 Central Nervous System
 351 Bacterial-gram negative
 352 Bacterial-gram positive
 353 Bacterial-unknown
 354 Fungal
 355 Viral
 356 Mycobacterial
 357 Protozoan/metazoan/parasitic
 358 Unknown agent
 359 Other agent
 360 Other site
 370 CMV Infection
 380 Warts
 381 Genital warts
 382 Non-genital warts
 383 Skin warts
 390 Unknown Site
 400 IMMUNOLOGIC/REJECTION
 410 Hyperacute rejection
 420 Acute rejection
 421 Vascular-humoral
 422 Vascular-cellular
 423 Vascular-mixed
 424 Vascular-necrotizing
 425 Interstitial-humoral
 426 Interstitial-cellular
 427 Interstitial-mixed
 428 Accelerated acute
 430 Chronic rejection
 431 Vascular-humoral
 432 Vascular-cellular
 433 Vascular-mixed
 434 Vascular-necrotizing
 435 Interstitial-humoral
 436 Interstitial-cellular
 437 Interstitial-mixed
 440 Serum sickness
 441 ATG (horse)
 442 ATG/ALS (rabbit)
 443 ATG/ALS (goat)
 444 Mouse monoclonal
 445 Other
 450 Anaphylaxis
 460 Recurrent renal disease in allograft
 470 De novo renal disease in allograft
 480 Chronic renal failure
 481 Uremia
 482 Renal allograft failure

500 NEOPLASTIC DISEASE
 510 Lymphoma/leukemia
 520 Skin
 521 Squamous cell
 522 Basal cell
 523 Malignant melanoma
 530 Uterine cervix
 540 Lung
 550 Bowel
 560 Central Nervous System
 590 Other

600 UROLOGIC COMPLICATIONS
 610 Urinary tract disorder
 611 Fistula
 612 Obstruction
 613 Calculi
 614 Urinoma
 615 Bladder leak
 616 Urologic technical failure
 620 Ureteral Disorder
 621 Necrosis
 622 Ureteral leak
 623 Microscopic
 630 Prostatic Disorder
 640 Hematuria
 641 Gross
 642 Microscopic
 650 Pyelonephritis
 651 Acute
 652 Chronic
 660 Lymphocele
 670 Papillary necrosis

700 OTHER ORGAN SYSTEM COMPLICATIONS
 710 Musculo-skeletal
 711 Aseptic necrosis
 712 Synovitis
 713 Osteopetrosis
 714 Osteomyelitis
 715 Arthralgia
 716 Arthritis
 720 Neurologic Complications
 (see 230, 350)
 721 Seizures
 722 Aphasia
 723 Meningitis
 724 Femoral nerve palsy

730	<u>Pulmonary Complications</u> (see 220, 330)	800	<u>IATROGENIC/SELF INDUCED</u>
731	(Upper respiratory infections (see 330))	810	<u>Substance abuse</u>
732	Pneumonia	811	Alcoholism
733	Empyema	812	Heroin
734	Lung abscess	813	Cocaine
735	Sinusitis	814	Amphetamines
736	Pleural effusion	815	Hallucinogenics
737	Transplant lung	816	Narcotics (other than heroin)
740	<u>Endocrine Complications</u>	819	Other
741	Steroid induced diabetes	820	<u>Substance Misuse by Patient</u>
742	Post operative diabetes (insulin independent)	821	Steroids
743	Post operative diabetes (insulin dependent)	822	Azathioprine
744	Hyperparathyroidism	823	Other immunosuppressives
745	Cushingoid changes	824	Non-compliant with therapy
749	Other	829	Other
750	<u>Hepatic Complications</u>	830	<u>Other Therapy Induced</u>
751	Hepatitis (Type A)	831	Suicide
752	Hepatitis (Type B)	832	Patient withdrawal from dialysis
753	Hepatitis (Non A-Non B)	833	Patient refuses immunosuppression
754	Hepatic insufficiency	834	Steroid psychosis
755	Cirrhosis	835	Neurosis
756	Cholecystitis	836	Psychosis
757	Drug-induced (see 810)	839	Other
759	Other	840	<u>Other Therapy Induced</u>
760	<u>G.I. Complications</u>	841	Medical withdrawal of Immunosuppressive by physician
761	Peptic ulcer disease	842	Air embolism
762	Upper GI bleed	843	Death-related to therapy
763	Lower GI bleed	850	<u>Immunotherapy Drug Related</u>
764	Pancreatitis/pancreatic necrosis	851	Cyclosporine nephrotoxicity
765	Fecal impaction	852	Cyclosporine hepatotoxicity
766	Diverticulitis	853	Azathioprine toxicity
767	Esophagitis	854	Steroid toxicity
768	Appendicitis	855	Acne/skin reaction/rash
769	Other	860	<u>Other Drug Induced</u>
770	<u>Ocular Complications</u>	870	<u>Other Complications</u>
771	Cataracts	871	Obesity
772	Glaucoma	872	Post op surgery
773	Blindness	873	Native neph
774	Retinitis	874	Pregnancy
775	Retinopathy	875	Gyn (condylomas) din pap smear
779	Other		
780	<u>Hematologic</u>		
781	Leukopenia		
782	Thrombocytopenia		
783	Anemia		
784	Pancytopenia		
789	Other		
790	<u>Metabolic</u>		
791	Hyperkalemia		
792	Acidosis		
793	Alkalosis		



APPENDIX E

STUDY ON IMMUNOSUPPRESSIVE APPROACHES TO THE TREATMENT
OF KIDNEY TRANSPLANT RECIPIENTS

BASELINE QUESTIONNAIRE



INTRODUCTION

As a participant in this study of kidney transplant recipients you will be asked to complete a questionnaire every three months until the conclusion of the study. This first questionnaire is intended to collect what we refer to as **baseline** data. Our goal is to get a clear picture of your current situation, although a few questions refer to various time periods before you received your kidney transplant. This information will enable us to track your progress following your transplant.

In completing this questionnaire we would like you to do your best to provide the information requested. We realize that some of the questions we have asked are not easy to answer. Where possible we would like you to consult your personal medical and financial records. The accuracy of the information you provide will be improved by doing so. This is particularly true of the questions on prescription drugs, costs, use of hospital services, and household income.

In responding you may at times wonder about the value of the information you are asked to provide, may dislike the content of some questions, or may feel that some questions are repeated. These responses are not unexpected and merely reflect the complexity of this study. If the questions cause you to develop concerns about your health, please consult your physician.

There may also be some questions that you would prefer not to answer. If you choose not to answer a question for any reason, please indicate this by writing "NO ANSWER" beside the question so we will know that you read the question and decided not to respond. Be assured that **YOU ARE NOT REQUIRED TO ANSWER ANY QUESTION IN THIS QUESTIONNAIRE**. As in any survey, we would like you to answer as many questions as you possibly can. If too many people choose not to answer the questions, the success of the study will be jeopardized.

If you should have any questions or are particularly troubled by the questionnaire, please do not hesitate to place a collect call to the Renal Transplantation Study Office at (206) 525-3130, extension 289. We will be happy to discuss the study with you.

6. What is your height?

_____ FEET and _____ INCHES

7. What is your current body weight?

_____ POUNDS

8. What was your body weight just before your kidney transplant?

_____ POUNDS

9. What is your current marital status?

(CIRCLE ONE)

MARRIED 01
WIDOWED 02
DIVORCED 03
SEPARATED 04
NEVER MARRIED 05

10. Does anyone live at your residence with you?

(CIRCLE ONE)

YES 01
NO 02 (SKIP TO Q.12)

11. Besides yourself, how many other people live in your household?

_____ PEOPLE

12. How many years of education have you completed?

_____ YEARS

KIDNEY TRANSPLANT RECIPIENT NUMBER: _____

DATE: _____

1. In what month and year were you first diagnosed as having kidney failure?

_____/_____
MONTH YEAR

2. On what date did you receive your current kidney transplant?

_____/_____/_____
MONTH DAY YEAR

3. What is your date of birth?

_____/_____/_____
MONTH DAY YEAR

4. What is your sex?

(CIRCLE ONE)

MALE 01

FEMALE 02

5. Which of the following best describes your racial or ethnic identification?

(CIRCLE ONE)

BLACK (NEGRO) 01

CHICANO (MEXICAN AMERICAN) 02

NATIVE AMERICAN (AMERICAN INDIAN, ESKIMO, ALEUT) 03

WHITE (CAUCASIAN) 04

ORIENTAL (ASIAN AMERICAN OR PACIFIC ISLANDER) 05

OTHER (SPECIFY) _____ 06

13. What is the highest degree you have obtained?

(CIRCLE ONE)

- NEVER GRADUATED FROM HIGH SCHOOL 01
- HIGH SCHOOL DIPLOMA 02
- COLLEGE/UNIVERSITY DEGREE 03
- ADVANCED DEGREE (M.A., M.S., Ph.D., M.D., J.D., etc.) 04

EMPLOYMENT

Many patients with chronic renal failure have experienced difficulties in keeping a permanent job or being able to take care of their household. For these reasons, we would like to carefully record information about your job-related experiences.

14. Since you finished your formal schooling, that is high school, college, or trade school, approximately how many years have you worked either full-time or part-time?

_____ YEARS

15. What was your work activity or employment status during the **YEAR PRIOR** to your kidney transplant?

(CIRCLE ONE)

- EMPLOYED FULL-TIME 01
- EMPLOYED PART-TIME 02
- EMPLOYED BUT TEMPORARILY LAID OFF 03 (GO TO Q.19)
- UNEMPLOYED, LOOKING FOR WORK 04 (GO TO Q.19)
- UNEMPLOYED, NOT LOOKING FOR WORK 05 (GO TO Q.19)
- UNABLE TO WORK BECAUSE OF HEALTH (DISABLED) 06 (GO TO Q.19)
- HOMEMAKER 07 (GO TO Q.19)
- STUDENT (FULL-TIME) 08 (GO TO Q.19)
- RETIRED 09 (GO TO Q.19)
- OTHER (SPECIFY) _____ ... 10

16. How often did you do the following kinds of things **on the job**? Did you have to do these activities often, sometimes, or rarely?

(CIRCLE ONE RESPONSE FOR EACH ACTIVITY)

	OFTEN	SOME- TIMES	RARELY
A. WALK	01	02	03
B. USE STAIRS OR INCLINES	01	02	03
C. STAND FOR LONG PERIODS	01	02	03
D. SIT FOR LONG PERIODS	01	02	03
E. STOOP, CROUCH, OR KNEEL	01	02	03
F. REACH	01	02	03
G. USE FINGERS TO GRASP OR HANDLE	01	02	03
H. USE YOUR EYES FOR INSPECTION OF THINGS	01	02	03
I. USE YOUR EYES FOR READING	01	02	03
J. LIFT OR CARRY WEIGHTS UP TO 10 POUNDS	01	02	03
K. LIFT OR CARRY WEIGHTS UP TO 25 POUNDS	01	02	03
L. LIFT OR CARRY WEIGHTS UP TO 50 POUNDS	01	02	03

17. Did the last employer you had before your transplant do anything special for you because of your health to make it easier for you to work at your job?

(CIRCLE ONE)

YES 01

NO 02 (SKIP TO Q. 19)

NO, HAD NO HEALTH PROBLEM AT THE TIME 02 (SKIP TO Q. 19)

18. What did he/she do?

(CIRCLE YES OR NO FOR EACH ITEM)

	YES	NO
A. GOT SOMEONE TO HELP YOU	01	02
B. CHANGED JOBS (TASKS) TO SOMETHING YOU COULD DO	01	02
C. HELPED YOU LEARN NEW SKILLS	01	02
D. SHORTENED WORK DAY	01	02
E. ALLOWED FLEXIBLE SCHEDULE	01	02
F. ALLOWED MORE BREAKS AND REST PERIODS	01	02
G. GOT SPECIAL EQUIPMENT FOR THE JOB	01	02
H. ARRANGED SPECIAL TRANSPORTATION	01	02
I. EXTENDED SICK LEAVE	01	02
J. OTHER (SPECIFY) _____ ...	01	02

19. Does your health keep you from working on a job for pay now?

(CIRCLE ONE)

YES 01
NO 02

20. Are you limited in the **KIND** of work for pay you can do because of your health?

(CIRCLE ONE)

YES 01
NO 02

21. Are you limited in the **AMOUNT** of work for pay you can do because of your health?

(CIRCLE ONE)

YES 01

NO 02

22. Are you **NOW ABLE** to work for pay full-time, part-time, or not at all?

(CIRCLE ONE)

FULL-TIME 01

PART-TIME 02

NOT AT ALL 03 (GO TO Q.24)

23. Are you **NOW ABLE** to work for pay regularly or can you work only occasionally or irregularly?

(CIRCLE ONE)

REGULARLY 01

OCCASIONALLY OR IRREGULARLY 02

24. What is your **CURRENT** work activity or employment status?

(CIRCLE ONE)

EMPLOYED FULL-TIME 01

EMPLOYED PART-TIME 02

EMPLOYED BUT TEMPORARILY LAID OFF 03 (GO TO Q.28)

UNEMPLOYED, LOOKING FOR WORK 04 (GO TO Q.28)

UNEMPLOYED, NOT LOOKING FOR WORK 05 (GO TO Q.28)

UNABLE TO WORK BECAUSE OF HEALTH (DISABLED) 06 (GO TO Q.28)

HOMEMAKER 07 (GO TO Q.28)

STUDENT (FULL-TIME) 08 (GO TO Q.28)

RETIRED 09 (GO TO Q.28)

OTHER (SPECIFY) 10

25. How satisfied are you with your present job?

(CIRCLE ONE)

COMPLETELY SATISFIED 01
VERY SATISFIED 02
SATISFIED 03
NEUTRAL 04
DISSATISFIED 05
VERY DISSATISFIED 06
COMPLETELY DISSATISFIED 07
NOT CURRENTLY EMPLOYED 08

26. Has your current employer done anything special for you now because of your health to make it easier for you to work at your job?

(CIRCLE ONE)

YES 01
NO 02 (SKIP TO Q.28)

27. What has he/she done?

(CIRCLE YES OR NO FOR EACH ITEM)

	YES	NO
A. GOT SOMEONE TO HELP YOU	01	02
B. MADE WORK A LITTLE EASIER OR CHANGED JOB (TASKS) TO SOMETHING YOU COULD DO	01	02
C. HELPED YOU LEARN NEW SKILLS	01	02
D. SHORTENED WORK DAY	01	02
E. CHANGED TIME YOU CAME TO AND LEFT WORK	01	02
F. ALLOWED YOU MORE BREAKS AND REST PERIODS	01	02
G. GOT SPECIAL EQUIPMENT FOR THE JOB	01	02
H. ARRANGED SPECIAL TRANSPORTATION	01	02
I. OTHER (SPECIFY) _____ ...	01	02
J. OTHER (SPECIFY) _____ ...	01	02

28. Do you do the housework in your home?

(CIRCLE ONE)

YES 01
NO 02 (SKIP TO Q.31)

29. Did you have any help with the housework before you got kidney disease?

(CIRCLE ONE)

YES 01
NO 02

30. Have you recently needed any special help to manage your home?

(CIRCLE ONE)

YES 01
NO 02

DAILY ACTIVITIES

We are also interested in changes that may have occurred in your daily activities since you received your kidney transplant. Some recipients find that they can do more than they were doing before their transplant; others have had to limit their activities.

31. How difficult is it for you to remember what you felt like **JUST BEFORE YOU HAD THE TRANSPLANT**; that is, when you were sick with kidney disease?

(CIRCLE ONE)

VERY DIFFICULT 01
 SOMEWHAT DIFFICULT 02
 A LITTLE DIFFICULT 03
 NOT AT ALL DIFFICULT 04

32. How difficult is it for you to remember what you felt like **BEFORE YOU WERE EVER SICK WITH KIDNEY DISEASE?**

(CIRCLE ONE)

VERY DIFFICULT 01
 SOMEWHAT DIFFICULT 02
 A LITTLE DIFFICULT 03
 NOT AT ALL DIFFICULT 04
 I HAVE ALWAYS HAD KIDNEY DISEASE 05

Please answer the following questions for both your **CURRENT** activity AND for the **YEAR BEFORE** you received your kidney transplant. The wording of these questions is slightly awkward because we are trying to cover two time periods without restating the questions.

33. When traveling around your community, does/did someone have to assist you because of your health?

(CIRCLE YES OR NO FOR EACH TIME PERIOD)

	YES	NO
A. CURRENTLY	01	02
B. ONE YEAR PRIOR TO TRANSPLANT	01	02

34. Do/Did you have to stay indoors most or all of the day because of your health?

(CIRCLE YES OR NO FOR EACH TIME PERIOD)

	YES	NO
A. CURRENTLY	01	02
B. ONE YEAR PRIOR TO TRANSPLANT	01	02

35. Are/Were you in a bed or chair for most or all of the day because of your health?

(CIRCLE YES OR NO FOR EACH TIME PERIOD)

	YES	NO
A. CURRENTLY	01	02
B. ONE YEAR PRIOR TO TRANSPLANT	01	02

36. Does/Did your health limit the kind of vigorous activities you can do, such as running, lifting heavy objects, or participating in strenuous sports?

(CIRCLE YES OR NO FOR EACH TIME PERIOD)

	YES	NO
A. CURRENTLY	01	02
B. ONE YEAR PRIOR TO TRANSPLANT	01	02

37. Do/Did you have any trouble either walking **SEVERAL BLOCKS** or climbing a **FEW FLIGHTS** of stairs, because of your health?

(CIRCLE YES OR NO FOR EACH TIME PERIOD)

	YES	NO
A. CURRENTLY	01	02
B. ONE YEAR PRIOR TO TRANSPLANT	01	02

38. Do/Did you have trouble bending, lifting, or stooping because of your health?

(CIRCLE YES OR NO FOR EACH TIME PERIOD)

	YES	NO
A. CURRENTLY	01	02
B. ONE YEAR PRIOR TO TRANSPLANT	01	02

39. Do/Did you have any trouble either walking **ONE BLOCK** or climbing **ONE FLIGHT** of stairs because of your health?

(CIRCLE YES OR NO FOR EACH TIME PERIOD)

	YES	NO
A. CURRENTLY	01	02
B. ONE YEAR PRIOR TO TRANSPLANT	01	02

40. Do/Did you need help in walking such as assistance by another person or by a cane, crutches, walker, artificial limbs, or braces?

(CIRCLE YES OR NO FOR EACH TIME PERIOD)

	YES	NO
A. CURRENTLY	01	02
B. ONE YEAR PRIOR TO TRANSPLANT	01	02

41. Are/Were you unable to do certain kinds or amounts of work, housework, or schoolwork because of your health?

(CIRCLE YES OR NO FOR EACH TIME PERIOD)

	YES	NO
A. CURRENTLY	01	02
B. ONE YEAR PRIOR TO TRANSPLANT	01	02

42. Does/Did your health keep you from working at a job, doing work around the house, or going to school?

(CIRCLE YES OR NO FOR EACH TIME PERIOD)

	YES	NO
A. CURRENTLY	01	02
B. ONE YEAR PRIOR TO TRANSPLANT	01	02

43. Do/Did you need help with eating, dressing, bathing, or using the toilet because of your health?

(CIRCLE YES OR NO FOR EACH TIME PERIOD)

	YES	NO
A. CURRENTLY	01	02
B. ONE YEAR PRIOR TO TRANSPLANT	01	02

44. Does/Did your health limit you in any way from doing anything you want to do?

(CIRCLE YES OR NO FOR EACH TIME PERIOD)

	YES	NO
A. CURRENTLY	01	02
B. ONE YEAR PRIOR TO TRANSPLANT	01	02

45. Does your health **NOW** limit your ability to:

(CIRCLE YES OR NO FOR EACH ITEM)

	YES	NO
A. REACH	01	02
B. USE FINGERS TO GRASP OR HANDLE	01	02
C. USE YOUR EYES FOR INSPECTION OF THINGS	01	02
D. USE YOUR EYES FOR READING	01	02
E. LIFT OR CARRY WEIGHTS UP TO 10 POUNDS	01	02
F. LIFT OR CARRY WEIGHTS UP TO 25 POUNDS	01	02
G. LIFT OR CARRY WEIGHTS UP TO 50 POUNDS	01	02

QUALITY OF LIFE

Next we would like you to answer a few questions about your life in general; for example, how you have been feeling and your satisfaction with life.

46. During the **PAST FEW WEEKS**, did you ever feel...

(CIRCLE YES OR NO FOR EACH ITEM)

	YES	NO
A. PARTICULARLY EXCITED OR INTERESTED IN SOMETHING?	01	02
B. SO RESTLESS THAT YOU COULDN'T SIT LONG IN A CHAIR?	01	02
C. PROUD BECAUSE SOMEONE COMPLIMENTED YOU ON SOMETHING YOU HAD DONE?	01	02
D. VERY LONELY OR REMOTE FROM OTHER PEOPLE?	01	02
E. PLEASED ABOUT HAVING ACCOMPLISHED SOMETHING?	01	02
F. BORED?	01	02
G. ON TOP OF THE WORLD?	01	02
H. DEPRESSED OR VERY UNHAPPY?	01	02
I. THAT THINGS WERE GOING YOUR WAY?	01	02
J. UPSET BECAUSE SOMEONE CRITICIZED YOU?	01	02

Now we would like for you to answer a few questions about how you have felt and how things have been within the **PAST MONTH**.

47. How have you been feeling in general during the **PAST MONTH**?

(CIRCLE ONE)

- | | |
|------------------------------------|----|
| IN EXCELLENT SPIRITS | 01 |
| IN VERY GOOD SPIRITS | 02 |
| IN GOOD SPIRITS MOSTLY | 03 |
| UP AND DOWN IN SPIRITS A LOT | 04 |
| IN LOW SPIRITS MOSTLY | 05 |
| IN VERY LOW SPIRITS | 06 |

48. Have you been bothered by nervousness or your nerves during the **PAST MONTH**?

(CIRCLE ONE)

- | | |
|--|----|
| EXTREMELY SO—TO THE POINT WHERE
YOU COULD NOT WORK OR TAKE CARE OF THINGS | 01 |
| VERY MUCH SO | 02 |
| QUITE A BIT | 03 |
| SOME—ENOUGH TO BE BOTHERED | 04 |
| A LITTLE | 05 |
| NOT AT ALL | 06 |

49. Have you been in firm control of your behavior, thoughts, emotions, **OR** feelings during the **PAST MONTH**?

(CIRCLE ONE)

- YES, DEFINITELY SO 01
- YES, FOR THE MOST PART 02
- GENERALLY SO 03
- NOT TOO WELL 04
- NO, ENOUGH TO BOTHER YOU SOMEWHAT 05
- NO, ENOUGH TO BOTHER YOU VERY MUCH 06

50. Have you felt so sad, discouraged, hopeless or had so many problems that you wondered if anything was worthwhile during the **PAST MONTH**?

(CIRCLE ONE)

- EXTREMELY SO—TO THE POINT WHERE
YOU HAVE JUST ABOUT GIVEN UP 01
- VERY MUCH SO 02
- QUITE A BIT 03
- SOME—ENOUGH TO BE BOTHERED 04
- A LITTLE 05
- NOT AT ALL 06

51. Have you been under or felt you were under any strain, stress, or pressure during the **PAST MONTH**?

(CIRCLE ONE)

- YES—ALMOST MORE PRESSURE THAN
YOU COULD BEAR OR STAND 01
- YES—QUITE A BIT OF PRESSURE 02
- YES—SOME - MORE THAN USUAL 03
- YES—SOME - BUT ABOUT USUAL 04
- YES—A LITTLE 05
- NOT AT ALL 06

52. How happy, satisfied, or pleased have you been with your personal life during the **PAST MONTH**?

(CIRCLE ONE)

EXTREMELY HAPPY—COULD NOT HAVE BEEN MORE SATISFIED OR PLEASED	01
VERY HAPPY	02
FAIRLY HAPPY	03
SATISFIED—PLEASED	04
SOMEWHAT DISSATISFIED	05
VERY DISSATISFIED	06

53. Have you had any reason to wonder if you were losing your mind, or losing control over the way you act, talk, think, or feel during the **PAST MONTH**?

(CIRCLE ONE)

NOT AT ALL	01
ONLY A LITTLE	02
SOME—BUT NOT ENOUGH TO BE CONCERNED OR WORRIED ABOUT	03
SOME AND A LITTLE CONCERNED ABOUT IT	04
SOME AND QUITE CONCERNED ABOUT IT	05
YES, VERY MUCH SO AND VERY CONCERNED ABOUT IT	06

54. Have you been anxious, worried, or upset during the **PAST MONTH**?

(CIRCLE ONE)

EXTREMELY SO—TO THE POINT OF BEING SICK OR ALMOST SICK	01
VERY MUCH SO	02
QUITE A BIT	03
SOME—ENOUGH TO BE BOTHERED	04
A LITTLE BIT	05
NOT AT ALL	06

55. Have you felt down-hearted and blue during the **PAST MONTH**?

(CIRCLE ONE)

- ALL OF THE TIME 01
- MOST OF THE TIME 02
- A GOOD BIT OF THE TIME 03
- SOME OF THE TIME 04
- A LITTLE OF THE TIME 05
- NONE OF THE TIME 06

56. Have you been feeling emotionally stable and sure of yourself during the **PAST MONTH**?

(CIRCLE ONE)

- ALL OF THE TIME 01
- MOST OF THE TIME 02
- A GOOD BIT OF THE TIME 03
- SOME OF THE TIME 04
- A LITTLE OF THE TIME 05
- NONE OF THE TIME 06

57. Some people feel they can run their lives pretty much the way they want to; others feel the problems of life are sometimes too big for them. Which one are you most like?

(CIRCLE ONE)

- CAN RUN OWN LIFE 01
- PROBLEMS OF LIFE TOO BIG 02

58. Up to now, have you been able to satisfy most of your ambitions in life or have you had to settle for less than you hoped for?

(CIRCLE ONE)

- SATISFIED MOST AMBITIONS 01
- HAVE HAD TO SETTLE FOR LESS 02

59. Do you think you have had a fair opportunity to make the most of your life or have you been held back in some ways?

(CIRCLE ONE)

HAVE HAD A FAIR OPPORTUNITY 01

HAVE BEEN HELD BACK 02

60. Compared to **OTHER PEOPLE YOU KNOW**, would you say that you have enjoyed your life up to now more than most people, about the same, or less than most people?

(CIRCLE ONE)

MORE 01

ABOUT THE SAME 02

LESS 03

61. Taking all things together, how would you say things are these days—would you say you're very happy, pretty happy, or not too happy?

(CIRCLE ONE)

VERY HAPPY 01

PRETTY HAPPY 02

NOT TOO HAPPY 03

62. If you were to compare your quality of life with that of **OTHER PEOPLE WHOM YOU KNOW**, would you say your quality of life is better than theirs, about the same, or lower than theirs?

(CIRCLE ONE)

BETTER 01

ABOUT THE SAME 02

LOWER 03

63. Comparing your health with that of **OTHER PEOPLE YOUR AGE**, would you say your health is better than theirs, about the same, or poorer than theirs?

(CIRCLE ONE)

BETTER 01
ABOUT THE SAME 02
POORER 03

64. The things people have—housing, car, furniture, recreation, and the like—make up their standard living. Some people are satisfied with their standard of living, others feel it is not as high as they would like. How satisfied are you with your standard of living?

(CIRCLE ONE)

COMPLETELY SATISFIED 01
VERY SATISFIED 02
SATISFIED 03
NEUTRAL 04
DISSATISFIED 05
VERY DISSATISFIED 06
COMPLETELY DISSATISFIED 07

65. All things considered, how would you rate your friendships—the time you spend with friends, the things you do together, the number of friends you have, as well as the particular people who are your friends?

(CIRCLE ONE)

COMPLETELY SATISFIED 01
VERY SATISFIED 02
SATISFIED 03
NEUTRAL 04
DISSATISFIED 05
VERY DISSATISFIED 06
COMPLETELY DISSATISFIED 07

66. How satisfied are you with your life as a whole these days?

(CIRCLE ONE)

COMPLETELY SATISFIED 01
VERY SATISFIED 02
SATISFIED 03
NEUTRAL 04
DISSATISFIED 05
VERY DISSATISFIED 06
COMPLETELY DISSATISFIED 07

67. All things considered, how satisfied are you with your family life—the time you spend and the things you do with members of your family?

(CIRCLE ONE)

COMPLETELY SATISFIED 01
VERY SATISFIED 02
SATISFIED 03
NEUTRAL 04
DISSATISFIED 05
VERY DISSATISFIED 06
COMPLETELY DISSATISFIED 07

68. (FOR MARRIED OR SEPARATED PATIENTS ONLY)

How satisfied are you with your marriage?

(CIRCLE ONE)

- COMPLETELY SATISFIED 01
- VERY SATISFIED 02
- SATISFIED 03
- NEUTRAL 04
- DISSATISFIED 05
- VERY DISSATISFIED 06
- COMPLETELY DISSATISFIED 07

69. How satisfied are you with your family's situation as far as savings and investments are concerned?

(CIRCLE ONE)

- COMPLETELY SATISFIED 01
- VERY SATISFIED 02
- SATISFIED 03
- NEUTRAL 04
- DISSATISFIED 05
- VERY DISSATISFIED 06
- COMPLETELY DISSATISFIED 07

70. Most people get sick now and then, and others, such as yourself, have had chronic health problems. Overall, how satisfied are you with your health at this time?

(CIR CLE ONE)

COMPLETELY SATISFIED	01
VERY SATISFIED	02
SATISFIED	03
NEUTRAL	04
DISSATISFIED	05
VERY DISSATISFIED	06
COMPLETELY DISSATISFIED	07

71. Here are some words and phrases which we would like you to use to describe how you feel about your present life. For example, if you think your present life is **very** "boring," put an X in the box right next to the word "boring." If you think it is **very** "interesting," put an X in the box right next to the word "interesting." If you think it is somewhere in between, put an X where you think it belongs. **Put an X in one box on every line.**

A. BORING	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	INTERESTING
B. ENJOYABLE	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	MISERABLE
C. EASY	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	HARD
D. USELESS	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	WORTHWHILE
E. FRIENDLY	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	LONELY
F. FULL	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	EMPTY
G. DISCOURAGING	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	HOPEFUL
H. TIED DOWN	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	FREE
I. DISAPPOINTING	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	REWARDING
J. BRINGS OUT THE BEST IN ME	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	DOESN'T GIVE ME MUCH CHANCE

HEALTH

Now we would like to know a little about your health.

72. How would you rate your overall health at the present time?

(CIRCLE ONE)

- EXCELLENT 01
GOOD 02
FAIR 03
POOR 04

73. Is your health now better, about the same, or worse than it was five years ago?

(CIRCLE ONE)

- BETTER 01
ABOUT THE SAME 02
WORSE 03

74. Is your health now better, about the same, or worse than it was **THE YEAR BEFORE** you had your kidney transplant?

(CIRCLE ONE)

- BETTER 01
ABOUT THE SAME 02
WORSE 03

75. **IN THE YEAR PRIOR TO YOUR TRANSPLANT**, how many times were you in the hospital **OVERNIGHT** for any condition?

NUMBER OF TIMES _____
(If "0", GO TO Q.77)

76. What is the total number of **NIGHTS** you spent in the hospital in the **YEAR PRIOR TO YOUR TRANSPLANT**?

_____ NIGHTS

77. Since you received your transplant, have you stayed home in bed because of any illness or injury?

(CIRCLE ONE)

YES 01

NO 02 (SKIP TO Q.79)

78. Since your transplant, how many **DAYS** have you stayed in bed all or most of the day?

_____ DAYS

79. Below is a list of symptoms and health-related problems. Just before you had your kidney transplant how often did you have each of the following? Did you have them very often, sometimes, rarely, or never?

(CIRCLE ONE RESPONSE FOR EACH SYMPTOM)

	OFTEN	SOME- TIMES	RARELY	NEVER
A. PAIN	01	02	03	04
B. TIRING EASILY, NO ENERGY	01	02	03	04
C. WEAKNESS, LACK OF STRENGTH	01	02	03	04
D. ACHES, SWELLING, SICK FEELING	01	02	03	04
E. FAINTING SPELLS, DIZZINESS	01	02	03	04
F. NERVOUSNESS TENSION, ANXIETY	01	02	03	04
G. SHORTNESS OF BREATH, TROUBLE BREATHING	01	02	03	04
H. DEPRESSION	01	02	03	04
I. TREMORS	01	02	03	04
J. MUSCLE WEAKNESS	01	02	03	04
K. TEMPERATURE SENSITIVITY	01	02	03	04
L. SEIZURES	01	02	03	04
M. EXTRA BODY HAIR GROWTH	01	02	03	04
N. HIGH POTASSIUM	01	02	03	04
O. HIGH CONCENTRATION OF URIC ACID IN BLOOD	01	02	03	04

80. Since you received your kidney transplant, how often have you had each of the following symptoms or health-related problems? Have you had them very often, sometimes, rarely, or never?

(CIRCLE ONE RESPONSE FOR EACH SYMPTOM)

	OFTEN	SOME- TIMES	RARELY	NEVER
A. PAIN	01	02	03	04
B. TIRING EASILY, NO ENERGY	01	02	03	04
C. WEAKNESS, LACK OF STRENGTH	01	02	03	04
D. ACHES, SWELLING, SICK FEELING	01	02	03	04
E. FAINTING SPELLS, DIZZINESS	01	02	03	04
F. NERVOUSNESS TENSION, ANXIETY	01	02	03	04
G. SHORTNESS OF BREATH, TROUBLE BREATHING	01	02	03	04
H. DEPRESSION	01	02	03	04
I. TREMORS	01	02	03	04
J. MUSCLE WEAKNESS	01	02	03	04
K. TEMPERATURE SENSITIVITY	01	02	03	04
L. SEIZURES	01	02	03	04
M. EXTRA BODY HAIR GROWTH	01	02	03	04
N. HIGH POTASSIUM	01	02	03	04
O. HIGH CONCENTRATION OF URIC ACID IN BLOOD	01	02	03	04

81. Which, if any, of the following conditions did you have before your kidney transplant, and which do you have now? If you had the condition before your transplant and you still have it, circle "both."

(CIRCLE ONE RESPONSE FOR EACH CONDITION)

	NEVER	BEFORE TRANSPLANT	NOW	BOTH
A. CANCER	01	02	03	04
B. CHRONIC LUNG DISORDER	01	02	03	04
C. STOMACH ULCER	01	02	03	04
D. COLITIS, GASTRITIS	01	02	03	04
E. CHRONIC KIDNEY DISORDER	01	02	03	04
F. DIABETES	01	02	03	04
G. HEPATITIS	01	02	03	04
H. OTHER LIVER DISORDER	01	02	03	04
I. HYPERTENSION	01	02	03	04
J. HARDENING OF ARTERIES OR ARTERIOSCLEROSIS	01	02	03	04
K. ANGINA, MYOCARDIAL INFARCTION	01	02	03	04
L. EPILEPTIC SEIZURES OR CONVULSIONS	01	02	03	04
M. CEREBROVASCULAR ACCIDENT, INCLUDING STROKE	01	02	03	04
N. BONE DISEASE	01	02	03	04
O. BACK OR SPINE DISORDER	01	02	03	04
P. PARALYSIS	01	02	03	04
Q. ARTHRITIS OR RHEUMATISM	01	02	03	04
R. MISSING FINGER, HAND, OR ARM, TOE, FOOT, OR LEG	01	02	03	04

(CIRCLE ONE RESPONSE FOR EACH CONDITION)

	NEVER	BEFORE TRANSPLANT	NOW	BOTH
S. VISION (SIGHT) DISORDER	01	02	03	04
T. HEARING DISORDER	01	02	03	04
U. NERVOUS OR EMOTIONAL PROBLEMS	01	02	03	04
V. MENTAL DISORDER	01	02	03	04
W. ALCOHOL OR DRUG PROBLEMS	01	02	03	04
X. SLEEP DISORDER	01	02	03	04
Y. SKIN DISORDER	01	02	03	04
Z. MIGRAINE	01	02	03	04
AA. GUM DISORDER	01	02	03	04

82. How do you feel about the way you look? Are you...

(CIRCLE ONE)

- VERY HAPPY 01
- FRETTY HAPPY 02
- NOT VERY HAPPY 03
- NOT AT ALL HAPPY WITH
YOUR PHYSICAL APPEARANCE? 04

83. Do you think you are...

(CIRCLE ONE)

- TOO FAT 01
- JUST RIGHT 02
- TOO THIN? 03

84. Does your transplant affect the way you look?

(CIRCLE ONE)

YES 01
NO 02

85. Thinking back over the times since you received your kidney transplant, how well do you think you have adjusted to it?

(CIRCLE ONE)

VERY WELL 01
FAIRLY WELL 02
NOT TOO WELL 03
FAIRLY POORLY 04
VERY POORLY 05

86. Has the time since your transplant been ...

(CIRCLE ONE)

ABOUT WHAT YOU EXPECTED 01
WORSE THAN YOU EXPECTED, OR 02
BETTER THAN YOU EXPECTED? 03

87. Thinking back over the time since you received your transplant, how often have you felt that it was a mistake to have a transplant?

(CIRCLE ONE)

NEVER 01
ALMOST NEVER 02
SOMETIMES 03
VERY OFTEN 04
ALWAYS 05

88. In general, do you feel that you were well informed by doctors and transplant center staff **BEFORE** the operation about the transplant procedure and recovery?

(CIRCLE ONE)

YES 01

NO 02

89. This question may be a little harder to answer and will require careful thought. Let us speculate for a moment. **Suppose** you could choose your length of life and state of health and were given the following choice. Consider your present level of health, in other words any pain, suffering, or immobility which you may experience because of your health. Suppose instead that you could have good health and avoid this pain and suffering, but at the cost of having a shorter life. Specifically, if you were able to give up a certain number of **DAYS OR WEEKS EACH YEAR** in return for **GOOD HEALTH** during the rest of the year, how much time, if any, would you be willing to give up each year?

NUMBER OF DAYS _____

or

NUMBER OF WEEKS _____

LIFESTYLE

The following questions concern your diet and exercise.

90. Which of the following diets, if any, are you currently on?

(CIRCLE YES OR NO FOR EACH TIME PERIOD)

	YES	NO
A. WEIGHT REDUCING	01	02
B. LOW CHOLESTEROL	01	02
C. LOW SALT	01	02
D. NO ADDED SALT	01	02
E. DIABETIC	01	02
F. OTHER (SPECIFY) _____ ...	01	02

91. If on a diet, how often, if at all, do you follow your diet as prescribed by your doctor?

(CIRCLE ONE)

ALWAYS	01
MOST OF THE TIME	02
SOME OF THE TIME	03
NEVER	04
NOT ON A SPECIAL DIET	05

92. If on a diet, how often, if at all, is your weight gain between your checkups higher than it should be?

(CIRCLE ONE)

FREQUENTLY	01
OCCASIONALLY	02
RARELY	03
NEVER	04
HAVE NOT HAD A CHECKUP	05

93. How often, if at all, do you take your drugs as prescribed by your doctor?

(CIRCLE ONE)

- ALWAYS 01
- MOST OF THE TIME 02
- SOME OF THE TIME 03
- NEVER 04

Next there are some questions about your current level of physical activity. Please regard the examples given as general guidelines relative to your physical condition. For example, if bowling is a **strenuous** activity for you, please count it as such.

94. During the past **MONTH**, about how many hours **PER WEEK** did you spend in **LIGHT** activities like these: -

- STANDING OR WALKING SLOWLY
- BOWLING
- FISHING QUIETLY
- PLAYING MUSICAL INSTRUMENT
- MOWING THE LAWN WITH POWER MOWER
- OTHER LIGHT ACTIVITIES?

(CIRCLE ONE)

- NO HOURS PER WEEK 01
- 5 HOURS OR LESS 02
- 6 TO 15 03
- 16 TO 25 04
- 26 TO 35 05
- 35 HOURS OR MORE 06

95. During the past **MONTH**, about how many hours **PER WEEK** did you spend in **MEDIUM** activities like these:

- BICYCLING
- PLAYING GOLF
- DANCING
- CANOEING (NOT WHITE WATER)
- DIGGING OR GARDENING
- DOING CARPENTRY
- SWIMMING SLOWLY
- OTHER MEDIUM ACTIVITIES?

(CIRCLE ONE)

NO HOURS PER WEEK 01
1 HOUR 02
2 TO 5 03
6 TO 10 04
11 TO 15 05
16 HOURS OR MORE 06

96. During the past **MONTH**, about how many hours **PER WEEK** did you spend in **STRENUOUS** activities like these:

- CARRYING HEAVY WEIGHTS (80 LBS. OR MORE)
- SHOVELING HEAVY LOADS
- JOGGING OR RUNNING FAST
- SKIING
- PLAYING FULL COURT BASKETBALL
- PLAYING HANDBALL OR SQUASH
- PLAYING TOUCH FOOTBALL
- OTHER STRENUOUS (HEAVY) ACTIVITIES?

(CIRCLE ONE)

NO HOURS PER WEEK 01
1 HOUR 02
2 TO 5 03
6 TO 10 04
11 TO 15 05
16 HOURS OR MORE 06

97. Which statement describes you best?

(CIRCLE ONE)

- NOT VERY ACTIVE, SITTING AND
WALKING MOSTLY 01
- A WEEKEND OR VACATION EXERCISER 02
- PHYSICALLY ACTIVE AT LEAST
1-2 TIMES DURING THE WEEK 03
- PHYSICALLY ACTIVE 3 OR MORE TIMES
DURING THE WEEK 04

98. Which of the following statements best describes your life during the **PAST MONTH**?

(CIRCLE ONE)

- WELL AND DOING MOST THINGS 01
- WELL BUT NOT PERFORMING MANY
CUSTOMARY ACTIVITIES 02
- UP MOST OF THE DAY BUT QUITE
RESTRICTED ACTIVITY 03
- CONFINED TO A WHEELCHAIR
WHEN OUT OF BED 04
- CONFINED TO BED BUT FEELING WELL 05
- CONFINED TO BED AND NOT FEELING WELL 06

PERSONAL ADJUSTMENT

Some transplant recipients adjust better than others to their transplant experience. The following questions provide some insight into how you have adjusted.

99. Because of your health do you think you need...

(CIRCLE ONE)

- A LOT OF EXTRA HELP TO GET THINGS DONE 01
- SOME EXTRA HELP TO GET THINGS DONE 02
- A LITTLE EXTRA HELP, OR 03
- NO MORE HELP THAN ANY HEALTHY PERSON? 04

100. Because of your health do you feel you...

(CIRCLE ONE)

- ARE MORE DEPENDENT ON OTHERS FOR
HELP THAN YOU WOULD LIKE TO BE, OR 01
- THAT YOU WOULD LIKE TO HAVE SOMEONE
YOU COULD DEPEND ON MORE, OR 02
- NEITHER? 03 (GO TO Q.102)

101. How much of a problem is your dependence upon others since you had your kidney transplant?

(CIRCLE ONE)

- A GREAT PROBLEM 01
- SOMEWHAT OF A PROBLEM 02
- A SMALL PROBLEM 03
- NO PROBLEM 04

102. How independent do you feel you are now with regard to managing your life?

(CIRCLE ONE)

- VERY INDEPENDENT 01
PRETTY INDEPENDENT 02
NOT VERY INDEPENDENT 03
NOT AT ALL INDEPENDENT 04

103. How worried were you about your finances **AT THE TIME OF THE TRANSPLANT?**

(CIRCLE ONE)

- EXTREMELY WORRIED 01
MODERATELY WORRIED 02
A LITTLE WORRIED 03
NOT AT ALL WORRIED 04

104. How worried are you about your finances **now?**

(CIRCLE ONE)

- EXTREMELY WORRIED 01
MODERATELY WORRIED 02
A LITTLE WORRIED 03
NOT AT ALL WORRIED 04

105. If you were to compare yourself now to the time before you had your kidney transplant, do you think you are generally...

(CIRCLE ONE)

- HAPPIER THAN YOU WERE BEFORE
YOU HAD A TRANSPLANT 01
LESS HAPPY, OR 02
ABOUT AS HAPPY AS YOU WERE BEFORE? 03
CAN'T REMEMBER HOW YOU FELT 04

106. Have you ever received any of the following rehabilitation services since you had your transplant?

(CIRCLE YES OR NO FOR EACH TIME PERIOD)

	YES	NO
A. COUNSELING AND GUIDANCE	01	02
B. PHYSICAL THERAPY	01	02
C. JOB TRAINING	01	02
D. JOB PLACEMENT	01	02
E. VOCATIONAL OR BUSINESS SCHOOL TRAINING	01	02
F. COLLEGE OR UNIVERSITY EDUCATION	01	02
G. PSYCHOTHERAPY	01	02
H. SPECIAL DEVICES (e.g., BRACE, ARTIFICIAL LIMB)	01	02
I. CANE TRAINING FOR THE BLIND	01	02

SOCIAL SERVICES

In the next group of questions we will be asking about your experiences with government programs that provide cash benefits or other services.

107. Have you **EVER** applied for any of the following kinds of benefits?

(CIRCLE YES OR NO FOR EACH BENEFIT)

	YES	NO
A. SOCIAL SECURITY RETIREMENT	01	02
B. SOCIAL SECURITY DISABILITY (GREEN CHECK)	01	02
C. SOCIAL SECURITY MEDICARE	01	02
D. SOCIAL SECURITY SUPPLEMENTAL SECURITY INCOME (SSI)(GOLD CHECK)	01	02
E. PUBLIC WELFARE OR ASSISTANCE	01	02
F. VETERAN'S ADMINISTRATION (VA) BENEFITS	01	02
G. WORKMEN'S COMPENSATION	01	02
H. FEDERAL, STATE, OR LOCAL HOUSING SUBSIDIES	01	02
I. FEDERAL FOOD STAMPS	01	02
J. MEDICAID	01	02
K. STATE EMPLOYMENT SERVICE	01	02
L. PRIVATE SOCIAL SERVICES	01	02
M. STATE SPONSORED REHABILITATION	01	02
N. SPECIAL INCOME TAX EXEMPTION DUE TO LEGAL BLINDNESS	01	02

108. Do you **CURRENTLY** receive any of the following? For each "YES" list approximately how much you receive from each benefit per month.

(CIRCLE YES OR NO FOR EACH BENEFIT—
FOR EACH YES, LIST AMOUNT)

	YES	NO	DOLLARS
A. SOCIAL SECURITY RETIREMENT OR DISABILITY BENEFITS (GREEN CHECK)	01	02	\$ _____
B. SUPPLEMENTAL SECURITY INCOME (SSI)(GOLD CHECK)	01	02	\$ _____
C. RAILROAD RETIREMENT BENEFITS	01	02	\$ _____
D. VETERANS ADMINISTRATION BENEFITS	01	02	\$ _____
E. UNEMPLOYMENT COMPENSATION	01	02	\$ _____
F. WORKMEN'S COMPENSATION	01	02	\$ _____
G. "AID TO FAMILIES WITH DEPENDENT CHILDREN" (AFDC) ASSISTANCE	01	02	\$ _____
H. PUBLIC WELFARE OR ASSISTANCE	01	02	\$ _____
I. CIVIL SERVICE BENEFITS	01	02	\$ _____
J. UNION OR EMPLOYER DISABILITY BENEFITS	01	02	\$ _____
K. UNION OR EMPLOYER RETIREMENT OR PENSION BENEFITS	01	02	\$ _____
L. ANY OTHER BENEFITS (SPECIFY) _____ ...	01	02	\$ _____

109. Now we would like you to answer two questions to get a picture of your current financial situation. This information is important because it gives us some idea of financial problems you may have because of your transplant. Approximately what was your total family income from all sources in 1985? Please include wages, salary, tips, commissions, and net income from own business, professional practice, partnership or farm, dividends, interest, annuities, rents, pension and disability benefits, social security, welfare payments, and gifts.

	APPROXIMATE 1985 INCOME BEFORE TAXES
A. YOUR WAGES AND/OR SALARY	\$ _____
B. SPOUSE WAGES AND/OR SALARY	\$ _____
C. INCOME FROM PENSIONS, SOCIAL SECURITY, DISABILITY BENEFITS	\$ _____
D. INCOME FROM ALL OTHER SOURCES	\$ _____
E. TOTAL	\$ <u> </u>

110. Finally, we would like to get a very rough idea of your general financial situation by comparing your assets with any debts that you may have. To do this, first estimate the amount of money that you would have if you were to sell your house, cars, and other personal property and then pay-off all mortgages, car loans, and other debts. Next, add to this any money that you have in checking and savings accounts, credit unions, stocks, bonds, and mutual funds. Roughly, how much do you think you would have?

(CIRCLE ONE)

LESS THAN \$10,000	01
\$10,000 - \$24,999	02
\$25,000 - \$49,999	03
\$50,000 - \$99,999	04
\$100,000 - \$199,000	05
\$200,000 - OR MORE	06

MEDICAL COSTS

One of the objectives of this study is to estimate the costs associated with kidney transplantation, including both the cost of the transplant operation and the cost of routine follow-up care. Many of these costs, with your written permission, will be obtained from the transplant center. However, other costs such as physician office visits, outpatient laboratory tests and prescription drugs are **not** included in your transplant center records. To get an accurate estimate of the **total** cost of your kidney transplant, we would like to get information on these costs from you.

111. Since you were discharged from the hospital following your transplant operation, have you been in the hospital overnight for any condition?

(CIRCLE ONE)

YES 01

NO 02 (GO TO Q.113)

112. For each hospital stay, please indicate on the table below the name of the hospital, the date admitted and the date discharged.

NAME OF HOSPITAL	DATE ADMITTED	DATE DISCHARGED
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

113. Since you were discharged from the hospital following your transplant operation, have you for any reason seen a doctor in an outpatient clinic or in the doctor's office? Include visits to all types of doctors (for routine check-ups as well as for illnesses), but **DO NOT** include doctor's visits while you were in the hospital.

(CIRCLE ONE)

YES 01

NO 02 (GO TO Q.115)

114. For each office visit, please indicate on the table below the date of the visit, the type of physician (for example, transplant surgeon, nephrologist, general or family practitioner) and the total physician's charge for the visit.

DATE OF VISIT	TYPE OF PHYSICIAN	TOTAL PHYSICIAN'S CHARGE
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

115. Since you were discharged from the hospital following your transplant operation, have you had X-rays, lab tests or diagnostic tests performed (chest or pelvic X-rays, renograms, blood tests, EKGs, urine tests, needle biopsies, etc.)? Include all tests performed on an outpatient basis, but **DO NOT** include lab tests that were performed while you were in the hospital.

(CIRCLE ONE)

YES 01

NO 02 (GO TO Q.117)

116. For each X-ray, lab test or diagnostic test performed, please indicate on the table below the date of the test, type of test performed, and total charge for the test.

DATE OF TEST	TYPE OF TEST	TOTAL CHARGE
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

117. Finally, we are interested in the cost of all drugs which you are currently taking that are prescribed by your doctor. On the table below, please provide the name of each drug, the number of times that you have obtained this drug since you were discharged from the hospital following your transplant operation, and the cost of refilling each prescription (Much of this information can be obtained from the labels on the drug bottles.)

NAME OF DRUG	NUMBER OF TIMES OBTAINED	COST OF EACH PRESCRIPTION
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

118. Have you had any difficulty paying for your immunosuppressive medications?

(CIRCLE ONE)

YES 01

NO 02 (GO TO Q.120)

119. Which of the following drugs have you had trouble paying for?

(CIRCLE ALL THAT APPLY)

A. CYCLOSPORINE 01

B. PREDNISONE (OR OTHER STEROID) 02

C. AZATHIOPRINE 03

D. OTHER (SPECIFY) _____ ... 04

E. OTHER (SPECIFY) _____ ... 05

120. Do you currently receive any assistance in paying for immunosuppressive drugs?

(CIRCLE ONE)

YES 01

NO, I PAY OUT-OF-POCKET 02 (GO TO Q.122)

121. From which of the following sources do you receive assistance in paying for your immunosuppressive drugs?

(CIRCLE ALL THAT APPLY)

A. PRIVATE INSURANCE 01

B. HOSPITAL OR TRANSPLANT CENTER 02

C. MEDICARE 03

D. MEDICAID 04

E. STATE KIDNEY PROGRAM 05

F. SPECIAL PATIENT FUND 06

G. OTHER (SPECIFY) _____ ... 07

NOTTINGHAM HEALTH PROFILE

INTRODUCTION

The Nottingham Health Profile is an easily completed questionnaire intended to provide us with a general description of your current health status. This measure as well as other questions you have answered will give us an opportunity to determine how well the questions you answer relate to other measures of health status. Thus, several of the questions you will answer here are similar to others you have answered in this questionnaire.

Listed below are some problems people may have in their daily life. Look down the list and Circle 01 for any problem you have at the moment. Circle 02 for any problem that you do not have. If you are not sure whether to say yes or no, circle whichever answer you think is **MORE TRUE** at the moment.

	YES	NO
122. I'm tired all the time	01	02
123. I have pain at night	01	02
124. Things are getting me down	01	02
125. I have unbearable pain	01	02
126. I take tablets to help me sleep	01	02
127. I've forgotten what it's like to enjoy myself	01	02
128. I'm feeling on edge	01	02
129. I find it painful to change position	01	02
130. I feel lonely	01	02
131. I can only walk about indoors	01	02
132. I find it hard to bend	01	02
133. Everything is an effort	01	02
134. I'm waking up in the early hours of the morning	01	02
135. I'm unable to walk at all	01	02
136. I'm finding it hard to make contact with people	01	02
137. The days seem to drag	01	02
138. I have trouble getting up and down stairs or steps	01	02
139. I find it hard to reach for things	01	02

REMEMBER, IF YOU ARE NOT SURE WHETHER TO ANSWER
YES OR NO TO A PROBLEM, CIRCLE WHICHEVER
ANSWER YOU THINK IS **MORE TRUE** AT THE MOMENT.

	YES	NO
140. I'm in pain when I walk	01	02
141. I lose my temper easily these days	01	02
142. I feel there is nobody I am close to	01	02
143. I lie awake for most of the night	01	02
144. I feel as if I'm losing control	01	02
145. I'm in pain when I'm standing	01	02
146. I find it hard to dress myself	01	02
147. I soon run out of energy	01	02
148. I find it hard to stand for long (for example, at the kitchen sink, waiting for a bus)	01	02
149. I'm in constant pain	01	02
150. It takes me a long time to get to sleep	01	02
151. I feel I am a burden to people	01	02
152. Worry is keeping me awake at night	01	02
153. I feel life is not worth living	01	02
154. I sleep badly at night	01	02
155. I'm finding it hard to get along with people	01	02
156. I need help to walk about outside (for example, a walking aid or someone to support me)	01	02
157. I'm in pain when going up and down stairs or steps	01	02
158. I wake up feeling depressed	01	02
159. I'm in pain when I'm sitting	01	02

NOW WE WOULD LIKE YOU TO THINK ABOUT THE ACTIVITIES
IN YOUR LIFE WHICH MAY BE AFFECTED BY HEALTH
PROBLEMS. PLEASE TURN OVER AND ANSWER THE
NEXT SECTION OF THE QUESTIONNAIRE

IN THE LIST BELOW, CIRCLE 01 FOR EACH ACTIVITY IN YOUR
LIFE WHICH IS BEING AFFECTED BY YOUR STATE OF HEALTH.
CIRCLE 02 FOR EACH ACTIVITY WHICH IS NOT BEING
AFFECTED, OR WHICH DOES NOT APPLY TO YOU

Is your present state of health causing problems with your...

	YES	NO
160. Job or work (that is, paid employment)	01	02
161. Looking after the home (Examples: cleaning and cooking, repairs, odd jobs around the home)	01	02
162. Social life (Examples: going out, seeing friends, going to a show)	01	02
163. Home life (That is: relationships with other people in your home)	01	02
164. Sex life	01	02
165. Interests and hobbies (Examples: sports, arts and crafts, do-it-yourself, etc.)	01	02
166. Vacation (Examples: summer and winter vacations, weekends away, etc.)	01	02

SICKNESS IMPACT PROFILE

INTRODUCTION

Transplant teams continue to concern themselves with the postoperative health status of transplant recipients. Researchers have developed many different health status measures. Depending upon how health status is defined, some of these measures are more extensive than others. The health status measure that follows, known as the Sickness Impact Profile, is among the most detailed available and is intended to measure the extent to which sickness has an impact on your ability to do certain activities. Some of the questions may seem quite similar to those you have just answered. However, it is important that we include them to maintain the standardized nature of the Sickness Impact Profile.

We realize that this questionnaire has already taken a considerable amount of your time and effort. You may want to stop at this point and complete this final part of the questionnaire tomorrow. It will probably take about 20 minutes to complete this part of the questionnaire. Instructions for the Sickness Impact Profile are on the following pages.

INSTRUCTIONS

PLEASE READ THE FOLLOWING INTRODUCTION BEFORE YOU READ THE QUESTIONNAIRE. IT IS VERY IMPORTANT THAT EVERYONE COMPLETING THE QUESTIONNAIRE FOLLOWS THE SAME INSTRUCTIONS.

INTRODUCTION TO RESPONDENT

You have certain activities that you do in carrying on your life. Sometimes you do all of these activities. Other times, because of your state of health, you don't do these activities in the usual way: you may cut some out; you may do some for shorter lengths of time; you may do some in different ways. These changes in your activities might be recent or longstanding. We are interested in learning about any changes that describe you today and are related to your state of health.

The questionnaire booklet lists statements that people have told us describe them when they are not completely well. Whether or not you consider yourself sick, there may be some statements that will stand out because they describe you today and are related to your state of health. As you read the questionnaire, think of yourself today. When you read a statement that you are sure describes you and is related to your health, place a check on the line to the right of the statement. For example:

I am not driving my car

☒ (026-031)

If you have not been driving for some time because of your health, and are still not driving today, you should respond to this statement.

On the other hand, if you never drive or are not driving today because your car is being repaired, the statement, "I am not driving my car" is not related to your health and you should not check it. If you simply are driving less, or are driving short distances, and feel that the statement only partially describes you, do not check it. In all of these cases you would leave the line to the right of the statement blank. For example:

I am not driving my car

☐ (026-031)

Remember that we want you to check this statement only if you are sure it describes you today and is related to your state of health.

Read the introduction to each group of statements and then consider the statements in the order listed. While some of the statements may not apply to you, we ask that you please read all of them. Check those that describe you as you go along. Some of the statements will differ only in a few words, so please read each one carefully. While you may go back to change a response, your first answer is usually the best. Please do not read ahead in the booklet.

Once you have started the questionnaire, it is very important that you complete it within one day (24 hours).

If you find it hard to keep your mind on the statements, take a short break and then continue. When you have read all of the statements on a page, put a check in the BOX in the lower right-hand corner. If you have any questions, please refer back to these instructions.

Please do not discuss the statements with anyone, including family members, while doing the questionnaire.

Now turn to the questionnaire booklet and read the statements. Remember we are interested in the recent or longstanding changes in your activities that are related to your health.

PLEASE RESPOND TO **ONLY** THOSE STATEMENTS THAT YOU ARE **SURE** DESCRIBE YOU TODAY AND ARE RELATED TO YOUR STATE OF HEALTH.

167. I spend much of the day lying down in order to rest _____ (083)
168. I sit during much of the day _____ (049)
169. I am sleeping or dozing most of the time—day and night _____ (104)
170. I lie down more often during the day in order to rest _____ (058)
171. I sit around half-asleep _____ (084)
172. I sleep less at night, for example, wake up too early,
don't fall asleep for a long time, awaken frequently _____ (061)
173. I sleep or nap more during the day _____ (060)

CHECK HERE WHEN YOU HAVE READ ALL STATEMENTS ON THIS PAGE

☐

PLEASE RESPOND TO ONLY THOSE STATEMENTS THAT YOU ARE SURE DESCRIBE YOU TODAY AND ARE RELATED TO YOUR STATE OF HEALTH.

- | | |
|---|-------------|
| 174. I say how bad or useless I am, for example, that I am a burden on others | _____ (087) |
| 175. I laugh or cry suddenly | _____ (068) |
| 176. I often moan and groan in pain or discomfort | _____ (069) |
| 177. I have attempted suicide | _____ (132) |
| 178. I act nervous or restless | _____ (046) |
| 179. I keep rubbing or holding areas of my body that hurt or are uncomfortable | _____ (062) |
| 180. I act irritable and impatient with myself, for example, talk badly
about myself, swear at myself, blame myself for things that happen | _____ (078) |
| 181. I talk about the future in a hopeless way | _____ (089) |
| 182. I get sudden frights | _____ (074) |

CHECK HERE WHEN YOU HAVE READ ALL STATEMENTS ON THIS PAGE

☐

PLEASE RESPOND TO **ONLY** THOSE STATEMENTS THAT YOU ARE **SURE** DESCRIBE YOU TODAY AND ARE RELATED TO YOUR STATE OF HEALTH.

- | | | |
|------|--|-------------|
| 183. | I make difficult moves with help, for example, getting into or out of cars, bathtubs | _____ (084) |
| 184. | I do not move into or out of bed or chair by myself but am moved by a person or mechanical aid | _____ (121) |
| 185. | I stand only for short periods of time | _____ (072) |
| 186. | I do not maintain balance | _____ (098) |
| 187. | I move my hands or fingers with some limitation or difficulty | _____ (064) |
| 188. | I stand up only with someone's help | _____ (100) |
| 189. | I kneel, stoop, or bend down only by holding on to something | _____ (064) |
| 190. | I am in a restricted position all the time | _____ (125) |
| 191. | I am very clumsy in body movements | _____ (068) |
| 192. | I get in and out of bed or chairs by grasping something for support or using a cane or walker | _____ (082) |
| 193. | I stay lying down most of the time | _____ (113) |
| 194. | I change position frequently | _____ (030) |
| 195. | I hold on to something to move myself around in bed | _____ (026) |
| 196. | I do not bathe myself completely, for example, require assistance with bathing | _____ (089) |
| 197. | I do not bathe myself at all, but am bathed by someone else | _____ (115) |
| 198. | I use bedpan with assistance | _____ (114) |

199. I have trouble getting shoes, socks, or stockings on _____ (057)
200. I do not have control of my bladder _____ (124)
201. I do not fasten my clothing, for example, require assistance with buttons, zippers, shoelaces _____ (074)
202. I spend most of the time partly undressed or in pajamas _____ (074)
203. I do not have control of my bowels _____ (128)
204. I dress myself, but do so very slowly _____ (043)
205. I get dressed only with someone's help _____ (088)

CHECK HERE WHEN YOU HAVE READ ALL STATEMENTS ON THIS PAGE

☐

THIS GROUP OF STATEMENTS HAS TO DO WITH ANY WORK YOU USUALLY DO IN CARING FOR YOUR HOME OR YARD. CONSIDERING JUST THOSE THINGS THAT YOU DO. PLEASE RESPOND TO **ONLY** THOSE STATEMENTS THAT YOU ARE **SURE** DESCRIBE YOU TODAY AND ARE RELATED TO YOUR STATE OF HEALTH.

206. I do work around the house only for short periods of time or rest often _____ (054)
207. I am doing less of the regular daily work around the house than I would usually do _____ (044)
208. I am not doing any of the regular daily work around the house that I would usually do _____ (086)
209. I am not doing any of the maintenance or repair work that I would usually do in my home or yard _____ (062)
210. I am not doing any of the shopping that I would usually do _____ (071)
211. I am not doing any of the house cleaning that I would usually do _____ (077)
212. I have difficulty doing handwork, for example, turning faucets, using kitchen gadgets, sewing, carpentry _____ (069)
213. I am not doing any of the clothes washing that I would usually do _____ (077)
214. I am not doing heavy work around the house _____ (044)
215. I have given up taking care of personal or household business affairs, for example, paying bills, banking, working on budget. _____ (064)

CHECK HERE WHEN YOU HAVE READ ALL STATEMENTS ON THIS PAGE

☐

(M-0719)

PLEASE RESPOND TO **ONLY** THOSE STATEMENTS THAT YOU ARE **SURE** DESCRIBE YOU TODAY AND ARE RELATED TO YOUR STATE OF HEALTH.

- | | |
|--|-------------|
| 216. I am getting around only within one building | _____ (086) |
| 217. I stay within one room | _____ (106) |
| 218. I am staying in bed more | _____ (081) |
| 219. I am staying in bed most of the time | _____ (109) |
| 220. I am not now using public transportation | _____ (041) |
| 221. I stay home most of the time | _____ (056) |
| 222. I am only going to places with restrooms nearby | _____ (056) |
| 223. I am not going into town | _____ (048) |
| 224. I stay away from home only for brief periods of time | _____ (054) |
| 225. I do not get around in the dark or in unlit places without someone's help | _____ (072) |

CHECK HERE WHEN YOU HAVE READ ALL STATEMENTS ON THIS PAGE

☐

PLEASE RESPOND TO **ONLY THOSE STATEMENTS THAT YOU ARE SURE DESCRIBE YOU TODAY AND ARE RELATED TO YOUR STATE OF HEALTH.**

- | | | |
|------|--|-------------|
| 226. | I am going out less to visit people | _____ (044) |
| 227. | I am not going out to visit people at all | _____ (101) |
| 228. | I show less interest in other people's problems, for example, don't listen when they tell me about their problems, don't offer to help | _____ (067) |
| 229. | I often act irritable toward those around me, for example, snap at people, give sharp answers, criticize easily | _____ (084) |
| 230. | I show less affection | _____ (052) |
| 231. | I am doing fewer social activities with groups of people | _____ (036) |
| 232. | I am cutting down the length of visits with friends | _____ (043) |
| 233. | I am avoiding social visits from others | _____ (080) |
| 234. | My sexual activity is decreased | _____ (051) |
| 235. | I often express concern over what might be happening to my health | _____ (052) |
| 236. | I talk less with those around me | _____ (056) |
| 237. | I make many demands, for example, insist that people do things for me, tell them how to do things | _____ (088) |
| 238. | I stay alone much of the time | _____ (086) |
| 239. | I act disagreeable to family members, for example, I act spiteful, I am stubborn | _____ (088) |
| 240. | I have frequent outbursts of anger at family members, for example, strike at them, scream, throw things at them | _____ (119) |
| 241. | I isolate myself as much as I can from the rest of the family | _____ (102) |

242. I am paying less attention to the children _____ (064)
243. I refuse contact with family members, for example, turn away from them _____ (115)
244. I am not doing the things I usually do to take care
of my children or family _____ (079)
245. I am not joking with family members as I usually do _____ (043)

CHECK HERE WHEN YOU HAVE READ ALL STATEMENTS ON THIS PAGE

☐

PLEASE RESPOND TO **ONLY** THOSE STATEMENTS THAT YOU ARE **SURE** DESCRIBE YOU TODAY AND ARE RELATED TO YOUR STATE OF HEALTH.

246. I walk shorter distances or stop to rest often _____ (048)
247. I do not walk up or down hills _____ (056)
248. I use stairs only with mechanical support, for example, handrail, cane, crutches _____ (067)
249. I walk up or down stairs only with assistance from someone else _____ (076)
250. I get around in a wheelchair _____ (096)
251. I do not walk at all _____ (105)
252. I walk by myself but with some difficulty, for example, limp, wobble, stumble, have stiff leg _____ (055)
253. I walk only with help from someone _____ (088)
254. I go up and down stairs more slowly, for example, one step at a time, stop often _____ (054)
255. I do not use stairs at all _____ (083)
256. I get around only by using a walker, crutches, cane, walls, or furniture _____ (079)
257. I walk more slowly _____ (035)

CHECK HERE WHEN YOU HAVE READ ALL STATEMENTS ON THIS PAGE



(AB-0777)

PLEASE RESPOND TO **ONLY** THOSE STATEMENTS THAT YOU ARE **SURE** DESCRIBE YOU TODAY AND ARE RELATED TO YOUR STATE OF HEALTH.

258. I am confused and start several actions at a time _____ (090)
259. I have more minor accidents, for example, drop things, trip and fall, bump into things _____ (075)
260. I react slowly to things that are said or done _____ (059)
261. I do not finish things I start _____ (067)
262. I have difficulty reasoning and solving problems, for example, making plans, making decisions, learning new things _____ (084)
263. I sometimes behave as if I were confused or disoriented in place or time, for example, where I am, who is around, directions, what day it is _____ (113)
264. I forget a lot, for example, things that happened recently, where I put things, appointments _____ (078)
265. I do not keep my attention on any activity for long _____ (067)
266. I make more mistakes than usual _____ (064)
267. I have difficulty doing activities involving concentration and thinking _____ (080)

CHECK HERE WHEN YOU HAVE READ ALL STATEMENTS ON THIS PAGE

☐

PLEASE RESPOND TO **ONLY** THOSE STATEMENTS THAT YOU ARE **SURE** DESCRIBE YOU TODAY AND ARE RELATED TO YOUR STATE OF HEALTH.

268. I am having trouble writing or typing _____ (070)
269. I communicate mostly by gestures, for example,
moving head, pointing, sign language _____ (102)
270. My speech is understood only by a few people who know me well _____ (093)
271. I often lose control of my voice when I talk, for example,
my voice gets louder or softer, trembles, changes unexpectedly _____ (083)
272. I don't write except to sign my name _____ (063)
273. I carry on a conversation only when very close
to the other person or looking at him _____ (067)
274. I have difficulty speaking, for example, get stuck,
stutter, stammer, slur my words _____ (076)
275. I am understood with difficulty _____ (087)
276. I do not speak clearly when I am under stress _____ (064)

CHECK HERE WHEN YOU HAVE READ ALL STATEMENTS ON THIS PAGE



THE NEXT GROUP OF STATEMENTS HAS TO DO WITH ANY WORK YOU USUALLY DO OTHER THAN MANAGING YOUR HOME. BY THIS WE MEAN ANYTHING THAT YOU REGARD AS WORK THAT YOU DO ON A REGULAR BASIS.

277. DO YOU USUALLY DO WORK OTHER THAN
MANAGING YOUR HOME?

YES

NO

➔ IF YOU ANSWERED YES, GO ON TO THE NEXT PAGE

➔ IF YOU ANSWERED NO:

278. ARE YOU RETIRED?

YES

NO

279. IF YOU ARE RETIRED, WAS YOUR
RETIREMENT RELATED TO YOUR HEALTH?

YES

NO

280. IF YOU ARE NOT RETIRED, BUT ARE
NOT WORKING, IS THIS RELATED TO
YOUR HEALTH?

YES

NO

➔ NOW SKIP THE NEXT PAGE

IF YOU ARE NOT WORKING AND IT IS **NOT** BECAUSE OF
YOUR HEALTH, PLEASE SKIP THIS PAGE

NOW CONSIDER THE WORK YOU DO AND RESPOND TO ONLY THOSE STATEMENTS THAT YOU ARE SURE DESCRIBE YOU TODAY AND ARE RELATED TO YOUR STATE OF HEALTH. (IF TODAY IS A SATURDAY OR SUNDAY OR SOME OTHER DAY THAT YOU WOULD USUALLY HAVE OFF, PLEASE RESPOND AS IF TODAY WERE A WORKING DAY.)

281. I am not working at all _____ (361)

(IF YOU CHECKED THIS STATEMENT, SKIP TO THE NEXT PAGE)

282. I am doing part of my job at home _____ (037)

283. I am not accomplishing as much as usual at work _____ (055)

284. I often act irritable toward my work associates, for example,
snap at them, give sharp answers, criticize easily _____ (080)

285. I am working shorter hours _____ (043)

286. I am doing only light work _____ (050)

287. I work only for short periods of time or take frequent rests _____ (061)

288. I am working at my usual job but with some changes,
for example, using different tools or special aids,
trading some tasks with other workers _____ (034)

289. I do not do my job as carefully and accurately as usual _____ (062)

CHECK HERE WHEN YOU HAVE READ ALL STATEMENTS ON THIS PAGE

☐

THIS GROUP OF STATEMENTS HAS TO DO WITH ACTIVITIES YOU USUALLY DO IN YOUR FREE TIME. THESE ACTIVITIES ARE THINGS THAT YOU MIGHT DO FOR RELAXATION, TO PASS THE TIME, OR FOR ENTERTAINMENT. PLEASE RESPOND TO **ONLY** THOSE STATEMENTS THAT YOU ARE **SURE** DESCRIBE YOU TODAY AND ARE RELATED TO YOUR STATE OF HEALTH.

290. I do my hobbies and recreation for shorter periods of time _____ (039)
291. I am going out for entertainment less often _____ (036)
292. I am cutting down on some of my usual inactive recreation and pastimes, for example, watching TV, playing cards, reading _____ (059)
293. I am not doing any of my usual inactive recreation and pastimes, for example, watching TV, playing cards, reading _____ (084)
294. I am doing more inactive pastimes in place of my other usual activities _____ (051)
295. I am doing fewer community activities _____ (033)
296. I am cutting down on some of my usual physical recreation or activities _____ (043)
297. I am not doing any of my usual physical recreation or activities _____ (077)

CHECK HERE WHEN YOU HAVE READ ALL STATEMENTS ON THIS PAGE

☐

PLEASE RESPOND TO **ONLY** THOSE STATEMENTS THAT YOU ARE **SURE** DESCRIBE YOU TODAY AND ARE RELATED TO YOUR STATE OF HEALTH.

298. I am eating much less than usual _____ (037)
299. I feed myself but only by using specially prepared food or utensils _____ (077)
300. I am eating special or different food, for example, soft
food, bland diet, low-salt, low-fat, low-sugar _____ (043)
301. I eat no food at all but am taking fluids _____ (104)
302. I just pick or nibble at my food _____ (059)
303. I am drinking less fluids _____ (036)
304. I feed myself with help from someone else _____ (099)
305. I do not feed myself at all, but must be fed _____ (117)
306. I am eating no food at all, nutrition is
taken through tubes or intravenous fluids _____ (133)

CHECK HERE WHEN YOU HAVE READ ALL STATEMENTS ON THIS PAGE

☐

CONCLUSION OF THE QUESTIONNAIRE

We at the Battelle Human Affairs Research Centers very much appreciate the time and effort you have put into this questionnaire. The information you have provided is essential to meeting the objectives of the Renal Transplantation Study. If you have any comments regarding the study, please record them below.

[illegible]

THANK YOU FOR YOUR COOPERATION

PLEASE RETURN THE COMPLETED QUESTIONNAIRE IN THE
ENCLOSED POSTAGE-PAID ENVELOPE.



APPENDIX F

STUDY ON IMMUNOSUPPRESSIVE APPROACHES TO THE TREATMENT
OF KIDNEY TRANSPLANT RECIPIENTS

FOLLOW-UP QUESTIONNAIRE



INTRODUCTION

As a participant in this study of kidney transplant recipients, you agreed to complete a followup questionnaire every three months. Even though you have previously answered all the questions in this questionnaire, we ask that you do so again. Our goal is to get a clear picture of your current situation at three month intervals. By examining changes in your life situation we will be able to track your progress and the progress of other transplant recipients following surgery.

As in the past, we would like you to do your best to provide all the information we have requested. You will note that we do not ask you to answer every question in the questionnaire. If for a particular question we indicate "DO NOT ANSWER THIS QUESTION," please skip the question and go on to the next question. We realize that it is not easy to answer all these questions. To assure the accuracy of your answers, it would be helpful if you would consult your personal medical and financial records. This is particularly true of the questions on prescription drugs, costs, use of hospital services, and household income. If the questions cause you to develop concerns about your health, please consult your physician.

There may also be some questions that you would prefer not to answer. If you choose not to answer a question for any reason, please indicate this by writing "NO ANSWER" beside the question so we will know that you read the question and decided not to respond. Be assured that **YOU ARE NOT REQUIRED TO ANSWER ANY QUESTION IN THIS QUESTIONNAIRE**. As in any survey, we would like you to answer as many questions as you possibly can. If too many people choose not to answer the questions, the success of the study will be jeopardized.

If you should have any questions or are particularly troubled by the questionnaire, please do not hesitate to place a collect call to the Renal Transplantation Study Office at (206) 525-3130, extension 289. We will be happy to discuss the study with you.



KIDNEY TRANSPLANT RECIPIENT NUMBER: _____

DATE: _____

Many patients who have received kidney transplants have often been on more than one treatment modality. In other words, few patients receive kidney transplants without ever having been on dialysis. It is of interest to us to know how your kidney transplant compares with other treatment modalities you have been on. Over time, perhaps, your feelings about certain modalities have changed.

1. Of the modalities you have been on for the treatment of kidney failure, which one have you liked most?

(CIRCLE ONE)

CONTINUOUS AMBULATORY PERITONEAL DIALYSIS (CAPD)	01
HOME HEMODIALYSIS	02
IN-CENTER HEMODIALYSIS	03
TRANSPLANTATION	04
INTERMITTENT PERITONEAL DIALYSIS	05
I HAVE ONLY BEEN ON TRANSPLANTATION	06

2. How satisfied have you been with your kidney transplant?

(CIRCLE ONE)

COMPLETELY SATISFIED	01
VERY SATISFIED	02
SATISFIED	03
NEUTRAL	04
DISSATISFIED	05
VERY DISSATISFIED	06
COMPLETELY DISSATISFIED	07

3. At any time have you regretted that you had a kidney transplant?

(CIRCLE ONE)

YES 01

NO 02 (SKIP TO Q.5)

4. Why have you regretted your transplant? (LIST REASONS)

EMPLOYMENT

Many patients with chronic renal failure have experienced difficulties in keeping a permanent job or being able to take care of their household. For these reasons, we would like you to carefully record information about your job-related experiences.

5. Does your health keep you from working on a job for pay now?

(CIRCLE ONE)

YES 01

NO 02

6. Are you limited in the **KIND** of work for pay you can do because of your health?

(CIRCLE ONE)

YES 01

NO 02

7. Are you limited in the **AMOUNT** of work for pay you can do because of your health?

(CIRCLE ONE)

YES 01

NO 02

8. Are you **NOW ABLE** to work for pay full-time, part-time, or not at all?

(CIRCLE ONE)

FULL-TIME 01

PART-TIME 02

NOT AT ALL 03 (GO TO Q.14)

9. Are you **NOW ABLE** to work for pay regularly or can you work only occasionally or irregularly?

(CIRCLE ONE)

REGULARLY 01

OCCASIONALLY OR IRREGULARLY 02

10. What is your **CURRENT** work activity or employment status?

(CIRCLE ONE)

EMPLOYED FULL-TIME 01

EMPLOYED PART-TIME 02

EMPLOYED BUT TEMPORARILY LAID OFF 03 (GO TO Q.14)

UNEMPLOYED, LOOKING FOR WORK 04 (GO TO Q.14)

UNEMPLOYED, NOT LOOKING FOR WORK 05 (GO TO Q.14)

UNABLE TO WORK BECAUSE OF HEALTH (DISABLED) 06 (GO TO Q.14)

HOMEMAKER 07 (GO TO Q.14)

STUDENT (FULL-TIME) 08 (GO TO Q.14)

RETIRED 09 (GO TO Q.14)

OTHER (SPECIFY) _____ ... 10

11. How satisfied are you with your present job?

(CIRCLE ONE)

COMPLETELY SATISFIED 01
VERY SATISFIED 02
SATISFIED 03
NEUTRAL 04
DISSATISFIED 05
VERY DISSATISFIED 06
COMPLETELY DISSATISFIED 07
NOT CURRENTLY EMPLOYED 08

12. Has your current employer done anything special for you now because of your health to make it easier for you to work at your job?

(CIRCLE ONE)

YES 01
NO 02 (SKIP TO Q.14)

13. What has he/she done?

(CIRCLE YES OR NO FOR EACH ITEM)

	YES	NO
A. GOT SOMEONE TO HELP YOU	01	02
B. MADE WORK A LITTLE EASIER OR CHANGED JOB (TASKS) TO SOMETHING YOU COULD DO	01	02
C. HELPED YOU LEARN NEW SKILLS	01	02
D. SHORTENED WORK DAY	01	02
E. CHANGED TIME YOU CAME TO AND LEFT WORK	01	02
F. ALLOWED YOU MORE BREAKS AND REST PERIODS	01	02
G. GOT SPECIAL EQUIPMENT FOR THE JOB	01	02
H. ARRANGED SPECIAL TRANSPORTATION	01	02
I. OTHER (SPECIFY) _____ ...	01	02
J. OTHER (SPECIFY) _____ ...	01	02

14. Do you do the housework in your home?

(CIRCLE ONE)

YES 01
NO 02 (SKIP TO Q.16)

15. Have you recently needed any special help to manage your home?

(CIRCLE ONE)

YES 01
NO 02

DAILY ACTIVITIES

We are also interested in changes that may have occurred in your daily activities since you received your kidney transplant. Some recipients find that they can do more than they were doing before their transplant; others have had to limit their activities.

16. When traveling around your community, does someone have to assist you because of your health?

(CIRCLE ONE)

YES 01

NO 02

17. Do you have to stay indoors most or all of the day because of your health?

(CIRCLE ONE)

YES 01

NO 02

18. Are you in a bed or chair for most or all of the day because of your health?

(CIRCLE ONE)

YES 01

NO 02

19. Does your health limit the kind of vigorous activities you can do, such as running, lifting heavy objects, or participating in strenuous sports?

(CIRCLE ONE)

YES 01

NO 02

20. Do you have any trouble either walking **SEVERAL BLOCKS** or climbing a **FEW FLIGHTS** of stairs, because of your health?

(CIRCLE ONE)

YES 01

NO 02

21. Do you have trouble bending, lifting, or stooping because of your health?

(CIRCLE ONE)

YES 01

NO 02

22. Do you have any trouble either walking **ONE BLOCK** or climbing **ONE FLIGHT** of stairs because of your health?

(CIRCLE ONE)

YES 01

NO 02

23. Do you need help in walking such as assistance by another person or by a cane, crutches, walker, artificial limbs, or braces?

(CIRCLE ONE)

YES 01

NO 02

24. Are you unable to do certain kinds or amounts of work, housework, or schoolwork because of your health?

(CIRCLE ONE)

YES 01

NO 02

25. Does your health keep you from working at a job, doing work around the house, or going to school?

(CIRCLE ONE)

YES 01

NO 02

26. Do you need help with eating, dressing, bathing, or using the toilet because of your health?

(CIRCLE ONE)

YES 01

NO 02

27. Does your health limit you in any way from doing anything you want to do?

(CIRCLE ONE)

YES 01

NO 02

28. Does your health **NOW** limit your ability to:

(CIRCLE YES OR NO FOR EACH ITEM)

	YES	NO
A. REACH	01	02
B. USE FINGERS TO GRASP OR HANDLE	01	02
C. USE YOUR EYES FOR INSPECTION OF THINGS	01	02
D. USE YOUR EYES FOR READING	01	02
E. LIFT OR CARRY WEIGHTS UP TO 10 POUNDS	01	02
F. LIFT OR CARRY WEIGHTS UP TO 25 POUNDS	01	02
G. LIFT OR CARRY WEIGHTS UP TO 50 POUNDS	01	02

QUALITY OF LIFE

Next we would like you to answer a few questions about your life in general; for example, how you have been feeling and your satisfaction with life.

29. Has there been a change in your marital status in the last 3 months?

(CIRCLE ONE)

YES 01

NO 02 (SKIP TO Q.31)

30. What is your current marital status?

(CIRCLE ONE)

MARRIED 01

WIDOWED 02

DIVORCED 03

SEPARATED 04

NEVER MARRIED 05

31. During the **PAST FEW WEEKS**, did you ever feel...

(CIRCLE YES OR NO FOR EACH ITEM)

	YES	NO
A. PARTICULARLY EXCITED OR INTERESTED IN SOMETHING?	01	02
B. SO RESTLESS THAT YOU COULDN'T SIT LONG IN A CHAIR?	01	02
C. PROUD BECAUSE SOMEONE COMPLIMENTED YOU ON SOMETHING YOU HAD DONE?	01	02
D. VERY LONELY OR REMOTE FROM OTHER PEOPLE?	01	02
E. PLEASED ABOUT HAVING ACCOMPLISHED SOMETHING?	01	02
F. BORED?	01	02
G. ON TOP OF THE WORLD?	01	02
H. DEPRESSED OR VERY UNHAPPY?	01	02
I. THAT THINGS WERE GOING YOUR WAY?	01	02
J. UPSET BECAUSE SOMEONE CRITICIZED YOU?	01	02

34. Have you been in firm control of your behavior, thoughts, emotions, **OR** feelings during the **PAST MONTH**?

(CIRCLE ONE)

- YES, DEFINITELY SO 01
- YES, FOR THE MOST PART 02
- GENERALLY SO 03
- NOT TOO WELL 04
- NO, ENOUGH TO BOTHER YOU SOMEWHAT 05
- NO, ENOUGH TO BOTHER YOU VERY MUCH 06

35. Have you felt so sad, discouraged, hopeless or had so many problems that you wondered if anything was worthwhile during the **PAST MONTH**?

(CIRCLE ONE)

- EXTREMELY SO—TO THE POINT WHERE
YOU HAVE JUST ABOUT GIVEN UP 01
- VERY MUCH SO 02
- QUITE A BIT 03
- SOME—ENOUGH TO BE BOTHERED 04
- A LITTLE 05
- NOT AT ALL 06

36. Have you been under or felt you were under any strain, stress, or pressure during the **PAST MONTH**?

(CIRCLE ONE)

- YES—ALMOST MORE PRESSURE THAN
YOU COULD BEAR OR STAND 01
- YES—QUITE A BIT OF PRESSURE 02
- YES—SOME — MORE THAN USUAL 03
- YES—SOME — BUT ABOUT USUAL 04
- YES—A LITTLE 05
- NOT AT ALL 06

37. How happy, satisfied, or pleased have you been with your personal life during the **PAST MONTH**?

(CIRCLE ONE)

EXTREMELY HAPPY—COULD NOT HAVE BEEN MORE SATISFIED OR PLEASED	01
VERY HAPPY	02
FAIRLY HAPPY	03
SATISFIED — PLEASED	04
SOMEWHAT DISSATISFIED	05
VERY DISSATISFIED	06

38. Have you had any reason to wonder if you were losing your mind, or losing control over the way you act, talk, think, or feel during the **PAST MONTH**?

(CIRCLE ONE)

NOT AT ALL	01
ONLY A LITTLE	02
SOME—BUT NOT ENOUGH TO BE CONCERNED OR WORRIED ABOUT	03
SOME AND A LITTLE CONCERNED ABOUT IT	04
SOME AND QUITE CONCERNED ABOUT IT	05
YES, VERY MUCH SO AND VERY CONCERNED ABOUT IT	06

39. Have you been anxious, worried, or upset during the **PAST MONTH**?

(CIRCLE ONE)

EXTREMELY SO—TO THE POINT OF BEING SICK OR ALMOST SICK	01
VERY MUCH SO	02
QUITE A BIT	03
SOME—ENOUGH TO BE BOTHERED	04
A LITTLE BIT	05
NOT AT ALL	06

40. Have you felt down-hearted and blue during the **PAST MONTH**?

(CIRCLE ONE)

ALL OF THE TIME 01
MOST OF THE TIME 02
A GOOD BIT OF THE TIME 03
SOME OF THE TIME 04
A LITTLE OF THE TIME 05
NONE OF THE TIME 06

41. Have you been feeling emotionally stable and sure of yourself during the **PAST MONTH**?

(CIRCLE ONE)

ALL OF THE TIME 01
MOST OF THE TIME 02
A GOOD BIT OF THE TIME 03
SOME OF THE TIME 04
A LITTLE OF THE TIME 05
NONE OF THE TIME 06

42. Taking all things together, how would you say things are these days—would you say you're very happy pretty happy, or not too happy?

(CIRCLE ONE)

VERY HAPPY 01
PRETTY HAPPY 02
NOT TOO HAPPY 03

43. If you were to compare your quality of life with that of **OTHER PEOPLE WHOM YOU KNOW**, would you say your quality of life is better than theirs, about the same, or lower than theirs?

(CIRCLE ONE)

BETTER 01
ABOUT THE SAME 02
LOWER 03

44. Comparing your health with that of **OTHER PEOPLE YOUR AGE**, would you say your health is better than theirs, about the same, or poorer than theirs?

(CIRCLE ONE)

BETTER 01
ABOUT THE SAME 02
POORER 03

45. The things people have—housing, car, furniture, recreation, and the like—make up their standard living. Some people are satisfied with their standard of living, others feel it is not as high as they would like. How satisfied are you with your standard of living?

(CIRCLE ONE)

COMPLETELY SATISFIED 01
VEPY SATISFIED 02
SATISFIED 03
NEUTRAL 04
DISSATISFIED 05
VERY DISSATISFIED 06
COMPLETELY DISSATISFIED 07

46. All things considered, how would you rate your friendships—the time you spend with friends, the things you do together, the number of friends you have, as well as the particular people who are your friends?

(CIRCLE ONE)

COMPLETELY SATISFIED 01
VERY SATISFIED 02
SATISFIED 03
NEUTRAL 04
DISSATISFIED 05
VERY DISSATISFIED 06
COMPLETELY DISSATISFIED 07

47. How satisfied are you with your life as a whole these days?

(CIRCLE ONE)

COMPLETELY SATISFIED 01
VERY SATISFIED 02
SATISFIED 03
NEUTRAL 04
DISSATISFIED 05
VERY DISSATISFIED 06
COMPLETELY DISSATISFIED 07

48. All things considered, how satisfied are you with your family life—the time you spend and the things you do with members of your family?

(CIRCLE ONE)

COMPLETELY SATISFIED 01
VERY SATISFIED 02
SATISFIED 03
NEUTRAL 04
DISSATISFIED 05
VERY DISSATISFIED 06
COMPLETELY DISSATISFIED 07

49. (FOR MARRIED OR SEPARATED PATIENTS ONLY)

How satisfied are you with your marriage?

(CIRCLE ONE)

COMPLETELY SATISFIED 01
VERY SATISFIED 02
SATISFIED 03
NEUTRAL 04
DISSATISFIED 05
VERY DISSATISFIED 06
COMPLETELY DISSATISFIED 07

50. How satisfied are you with your family's situation as far as savings and investments are concerned?

(CIRCLE ONE)

COMPLETELY SATISFIED 01
VERY SATISFIED 02
SATISFIED 03
NEUTRAL 04
DISSATISFIED 05
VERY DISSATISFIED 06
COMPLETELY DISSATISFIED 07

51. Most people get sick now and then, and others, such as yourself, have had chronic health problems. Overall, how satisfied are you with your health at this time?

(CIRCLE ONE)

COMPLETELY SATISFIED 01
VERY SATISFIED 02
SATISFIED 03
NEUTRAL 04
DISSATISFIED 05
VERY DISSATISFIED 06
COMPLETELY DISSATISFIED 07

HEALTH

Now we would like to know a little about your health.

52. How would you rate your overall health at the present time?

(CIRCLE ONE)

EXCELLENT 01
GOOD 02
FAIR 03
POOR 04

53. Is your health now better, about the same, or worse than it was **THE YEAR BEFORE** you had your kidney transplant?

(CIRCLE ONE)

BETTER 01
ABOUT THE SAME 02
WORSE 03

54. In the past 3 months, have you stayed home in bed because of any illness or injury?

(CIRCLE ONE)

YES 01
NO 02 (SKIP TO Q.56)

55. In the past 3 months, how many **DAYS** have you stayed in bed all or most of the day?

_____ DAYS

56. In the past 3 months, how often have you had each of the following symptoms or health-related problems? Have you had them very often, sometimes, rarely, or never?

(CIRCLE ONE RESPONSE FOR EACH SYMPTOM)

	OFTEN	SOME- TIMES	RARELY	NEVER
A. PAIN	01	02	03	04
B. TIRING EASILY, NO ENERGY	01	02	03	04
C. WEAKNESS, LACK OF STRENGTH	01	02	03	04
D. ACHES, SWELLING, SICK FEELING	01	02	03	04
E. FAINTING SPELLS, DIZZINESS	01	02	03	04
F. NERVOUSNESS TENSION, ANXIETY	01	02	03	04
G. SHORTNESS OF BREATH, TROUBLE BREATHING	01	02	03	04
H. DEPRESSION	01	02	03	04
I. TREMORS	01	02	03	04
J. MUSCLE WEAKNESS	01	02	03	04
K. TEMPERATURE SENSITIVITY	01	02	03	04
L. SEIZURES	01	02	03	04
M. EXTRA BODY HAIR GROWTH	01	02	03	04
N. HIGH POTASSIUM	01	02	03	04
O. HIGH CONCENTRATION OF URIC ACID IN BLOOD	01	02	03	04

57. Which, if any, of the following conditions have you developed in the past 3 months.

(CIRCLE YES OR NO FOR EACH CONDITION)

	YES	NO
A. CANCER	01	02
B. CHRONIC LUNG DISORDER	01	02
C. STOMACH ULCER	01	02
D. COLITIS, GASTRITIS	01	02
E. CHRONIC KIDNEY DISORDER	01	02
F. DIABETES	01	02
G. HEPATITIS	01	02
H. OTHER LIVER DISORDER	01	02
I. HYPERTENSION	01	02
J. HARDENING OF ARTERIES OR ARTERIOSCLEROSIS	01	02
K. ANGINA, MYOCARDIAL INFARCTION	01	02
L. EPILEPTIC SEIZURES OR CONVULSIONS	01	02
M. CEREBROVASCULAR ACCIDENT, INCLUDING STROKE	01	02
N. BONE DISEASE	01	02
O. BACK OR SPINE DISORDER	01	02
P. PARALYSIS	01	02
Q. ARTHRITIS OR RHEUMATISM	01	02
R. LOSS OF FINGER, HAND, OR ARM, TOE, FOOT, OR LEG	01	02

(CIRCLE YES OR NO FOR EACH CONDITION)

	YES	NO
S. VISION (SIGHT) DISORDER	01	02
T. HEARING DISORDER	01	02
U. NERVOUS OR EMOTIONAL PROBLEMS	01	02
V. MENTAL DISORDER	01	02
W. ALCOHOL OR DRUG PROBLEMS	01	02
X. SLEEP DISORDER	01	02
Y. SKIN DISORDER	01	02
Z. MIGRAINE	01	02
AA. GUM DISORDER	01	02

58. How do you feel about the way you look? Are you...

(CIRCLE ONE)

VERY HAPPY 01
PRETTY HAPPY 02
NOT VERY HAPPY 03
NOT AT ALL HAPPY WITH
YOUR PHYSICAL APPEARANCE? 04

59. Do you think you are...

(CIRCLE ONE)

TOO FAT 01
JUST RIGHT 02
TOO THIN? 03

60. Does your transplant affect the way you look?

(CIRCLE ONE)

YES 01

NO 02

61. Thinking back over the times since you received your kidney transplant, how well do you think you have adjusted to it?

(CIRCLE ONE)

VERY WELL 01

FAIRLY WELL 02

NOT TOO WELL 03

FAIRLY POORLY 04

VERY POORLY 05

62. Has the time since your transplant been ...

(CIRCLE ONE)

ABOUT WHAT YOU EXPECTED 01

WORSE THAN YOU EXPECTED, OR 02

BETTER THAN YOU EXPECTED? 03

63. Thinking back over the time since you received your transplant, how often have you felt that it was a mistake to have a transplant?

(CIRCLE ONE)

NEVER 01

ALMOST NEVER 02

SOMETIMES 03

VERY OFTEN 04

ALWAYS 05

LIFESTYLE

The following questions concern your diet and exercise.

64. Which of the following diets, if any, are you currently on?

(CIRCLE YES OR NO FOR EACH ITEM)

	YES	NO
A. WEIGHT REDUCING	01	02
B. LOW CHOLESTEROL	01	02
C. LOW SALT	01	02
D. NO ADDED SALT	01	02
E. DIABETIC	01	02
F. OTHER (SPECIFY) _____ ...	01	02

65. If on a diet, how often, if at all, do you follow your diet as prescribed by your doctor?

(CIRCLE ONE)

ALWAYS	01
MOST OF THE TIME	02
SOME OF THE TIME	03
NEVER	04
NOT ON A SPECIAL DIET	05

66. If on a diet, how often, if at all, is your weight gain between your checkups higher than it should be?

(CIRCLE ONE)

FREQUENTLY	01
OCCASIONALLY	02
RARELY	03
NEVER	04
HAVE NOT HAD A CHECKUP	05

67. How often, if at all, do you take your drugs as prescribed by your doctor?

(CIRCLE ONE)

- ALWAYS 01
- MOST OF THE TIME 02
- SOME OF THE TIME 03
- NEVER 04

Next there are some questions about your current level of physical activity. Please regard the examples given as general guidelines relative to your physical condition. For example, if bowling is a **strenuous** activity for you, please count it as such.

68. During the past **MONTH**, about how many hours **PER WEEK** did you spend in **LIGHT** activities like these:

- STANDING OR WALKING SLOWLY
- BOWLING
- FISHING QUIETLY
- PLAYING MUSICAL INSTRUMENT
- MOWING THE LAWN WITH POWER MOWER
- OTHER LIGHT ACTIVITIES?

(CIRCLE ONE)

- NO HOURS PER WEEK 01
- 5 HOURS OR LESS 02
- 6 TO 15 03
- 16 TO 25 04
- 26 TO 35 05
- 36 HOURS OR MORE 06

69. During the past **MONTH**, about how many hours **PER WEEK** did you spend in **MEDIUM** activities like these:

- BICYCLING
- PLAYING GOLF
- DANCING
- CANOEING (NOT WHITE WATER)
- DIGGING OR GARDENING
- DOING CARPENTRY
- SWIMMING SLOWLY
- OTHER MEDIUM ACTIVITIES?

(CIRCLE ONE)

NO HOURS PER WEEK 01
1 HOUR 02
2 TO 5 03
6 TO 10 04
11 TO 15 05
16 HOURS OR MORE 06

70. During the past **MONTH**, about how many hours **PER WEEK** did you spend in **STRENUOUS** activities like these:

- CARRYING HEAVY WEIGHTS (80 LBS. OR MORE)
- SHOVELING HEAVY LOADS
- JOGGING OR RUNNING FAST
- SKIING
- PLAYING FULL COURT BASKETBALL
- PLAYING HANDBALL OR SQUASH
- PLAYING TOUCH FOOTBALL
- OTHER STRENUOUS (HEAVY) ACTIVITIES?

(CIRCLE ONE)

NO HOURS PER WEEK 01
1 HOUR 02
2 TO 5 03
6 TO 10 04
11 TO 15 05
16 HOURS OR MORE 06

71. Which statement describes you best?

(CIRCLE ONE)

- NOT VERY ACTIVE, SITTING AND
WALKING MOSTLY 01
- A WEEKEND OR VACATION EXERCISER 02
- PHYSICALLY ACTIVE AT LEAST
1-2 TIMES DURING THE WEEK 03
- PHYSICALLY ACTIVE 3 OR MORE TIMES
DURING THE WEEK 04

72. Which of the following statements best describes you during the **PAST MONTH**?

(CIRCLE ONE)

- WELL AND DOING MOST THINGS 01
- WELL BUT NOT PERFORMING MANY
CUSTOMARY ACTIVITIES 02
- UP MOST OF THE DAY BUT QUITE
RESTRICTED ACTIVITY 03
- CONFINED TO A WHEELCHAIR
WHEN OUT OF BED 04
- CONFINED TO BED BUT FEELING WELL 05
- CONFINED TO BED AND NOT FEELING WELL 06

PERSONAL ADJUSTMENT

Some transplant recipients adjust better than others to their transplant experience. The following questions provide some insight into how you have adjusted.

73. Because of your health do you think you need...

(CIRCLE ONE)

- A LOT OF EXTRA HELP TO GET THINGS DONE 01
- SOME EXTRA HELP TO GET THINGS DONE 02
- A LITTLE EXTRA HELP, OR 03
- NO MORE HELP THAN ANY HEALTHY PERSON? 04

74. Because of your health do you feel you...

(CIRCLE ONE)

- ARE MORE DEPENDENT ON OTHERS FOR
HELP THAN YOU WOULD LIKE TO BE, OR 01
- THAT YOU WOULD LIKE TO HAVE SOMEONE
YOU COULD DEPEND ON MORE, OR 02
- NEITHER? 03 (GO TO Q.76)

75. How much of a problem is your dependence upon others since you had your kidney transplant?

(CIRCLE ONE)

- A GREAT PROBLEM 01
- SOMEWHAT OF A PROBLEM 02
- A SMALL PROBLEM 03
- NO PROBLEM 04

76. How independent do you feel you are now with regard to managing your life?

(CIRCLE ONE)

- VERY INDEPENDENT 01
PRETTY INDEPENDENT 02
NOT VERY INDEPENDENT 03
NOT AT ALL INDEPENDENT 04

77. How worried are you about your finances **now**?

(CIRCLE ONE)

- EXTREMELY WORRIED 01
MODERATELY WORRIED 02
A LITTLE WORRIED 03
NOT AT ALL WORRIED 04

78. If you were to compare yourself now to the time before you had your kidney transplant, do you think you are generally...

(CIRCLE ONE)

- HAPPIER THAN YOU WERE BEFORE
YOU HAD A TRANSPLANT 01
LESS HAPPY, OR 02
ABOUT AS HAPPY AS YOU WERE BEFORE? 03
CAN'T REMEMBER HOW YOU FELT 04

79. Have you ever received any of the following rehabilitation services within the past 3 months?

(CIRCLE YES OR NO FOR EACH ITEM)

	YES	NO
A. COUNSELING AND GUIDANCE	01	02
B. PHYSICAL THERAPY	01	02
C. JOB TRAINING	01	02
D. JOB PLACEMENT	01	02
E. VOCATIONAL OR BUSINESS SCHOOL TRAINING	01	02
F. COLLEGE OR UNIVERSITY EDUCATION	01	02
G. PSYCHOTHERAPY	01	02
H. SPECIAL DEVICES (e.g., BRACE, ARTIFICIAL LIMB)	01	02
I. CANE TRAINING FOR THE BLIND	01	02

SOCIAL SERVICES

In the next group of questions we will be asking about your experiences with government programs that provide cash benefits or other services.

80. In the past 3 months, have you applied for any of the following kinds of benefits?

(CIRCLE YES OR NO FOR EACH BENEFIT)

	YES	NO
A. SOCIAL SECURITY RETIREMENT	01	02
B. SOCIAL SECURITY DISABILITY (GREEN CHECK)	01	02
C. SOCIAL SECURITY MEDICARE	01	02
D. SOCIAL SECURITY SUPPLEMENTAL SECURITY INCOME (SSI)(GOLD CHECK)	01	02
E. PUBLIC WELFARE OR ASSISTANCE	01	02
F. VETERAN'S ADMINISTRATION (VA) BENEFITS	01	02
G. WORKMEN'S COMPENSATION	01	02
H. FEDERAL, STATE, OR LOCAL HOUSING SUBSIDIES	01	02
I. FEDERAL FOOD STAMPS	01	02
J. MEDICAID	01	02
K. STATE EMPLOYMENT SERVICE	01	02
L. PRIVATE SOCIAL SERVICES	01	02
M. STATE SPONSORED REHABILITATION	01	02
N. SPECIAL INCOME TAX EXEMPTION DUE TO LEGAL BLINDNESS	01	02

81. Do you **CURRENTLY** receive any of the following? For each "YES" list approximately how much you receive from each benefit per month.

(CIRCLE YES OR NO FOR EACH BENEFIT-
FOR EACH YES, LIST AMOUNT)

	YES	NO	DOLLARS
A. SOCIAL SECURITY RETIREMENT OR DISABILITY BENEFITS (GREEN CHECK)	01	02	\$ _____
B. SUPPLEMENTAL SECURITY INCOME (SSI)(GOLD CHECK)	01	02	\$ _____
C. RAILROAD RETIREMENT BENEFITS	01	02	\$ _____
D. VETERANS ADMINISTRATION BENEFITS	01	02	\$ _____
E. UNEMPLOYMENT COMPENSATION	01	02	\$ _____
F. WORKMEN'S COMPENSATION	01	02	\$ _____
G. "AID TO FAMILIES WITH DEPENDENT CHILDREN" (AFDC) ASSISTANCE	01	02	\$ _____
H. PUBLIC WELFARE OR ASSISTANCE	01	02	\$ _____
I. CIVIL SERVICE BENEFITS	01	02	\$ _____
J. UNION OR EMPLOYER DISABILITY BENEFITS	01	02	\$ _____
K. UNION OR EMPLOYER RETIREMENT OR PENSION BENEFITS	01	02	\$ _____
L. ANY OTHER BENEFITS (SPECIFY) _____ ...	01	02	\$ _____

82. Now we would like you to answer two questions to get a picture of your current financial situation. This information is important because it gives us some idea of financial problems you may have because of your transplant. Approximately what was your total family income from all sources in 1986? Please include wages, salary, tips, commissions, and net income from own business, professional practice, partnership or farm, dividends, interest, annuities, rents, pension and disability benefits, social security, welfare payments, and gifts.

	APPROXIMATE 1986 INCOME BEFORE TAXES
A. YOUR WAGES AND/OR SALARY	\$ _____
B. SPOUSE WAGES AND/OR SALARY	\$ _____
C. INCOME FROM PENSIONS, SOCIAL SECURITY, DISABILITY BENEFITS	\$ _____
D. INCOME FROM ALL OTHER SOURCES	\$ _____
E. TOTAL	\$ _____

83. Finally, we would like to get a very rough idea of your general financial situation by comparing your assets with any debts that you may have. To do this, first estimate the amount of money that you would have if you were to sell your house, cars, and other personal property and then pay-off all mortgages, car loans, and other debts. Next, add to this any money that you have in checking and savings accounts, credit unions, stocks, bonds, and mutual funds. Roughly, how much do you think you would have?

(CIRCLE ONE)

LESS THAN \$10,000	01
\$10,000 — \$24,999	02
\$25,000 — \$49,999	03
\$50,000 — \$99,999	04
\$100,000 — \$199,000	05
\$200,000 — OR MORE	06

MEDICAL COSTS

One of the objectives of this study is to estimate the costs associated with kidney transplantation, including both the cost of the transplant operation and the cost of routine follow-up care. Many of these costs, with your written permission, will be obtained from the transplant center. However, other costs such as physician office visits, outpatient laboratory tests and prescription drugs are **not** included in your transplant center records. To get an accurate estimate of the **total** cost of your kidney transplant, we would like to get information on these costs from you.

84. In the past 3 months, have you been in the hospital overnight for any condition?

(CIRCLE ONE)

YES 01

NO 02 (SKIP TO Q.86)

85. For each hospital stay, please indicate on the table below the name of the hospital, the date admitted and the date discharged.

NAME OF HOSPITAL	DATE ADMITTED	DATE DISCHARGED
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

86. In the past 3 months, have you for any reason seen a doctor in an outpatient clinic or in the doctor's office? Include visits to all types of doctors (for routine check-ups as well as for illnesses), but **DO NOT** include doctor's visits while you were in the hospital

(CIRCLE ONE)

YES 01

NO 02 (SKIP TO Q.88)

87. For each office visit, please indicate on the table below the date of the visit, the type of physician (for example, transplant surgeon, nephrologist, general or family practitioner) and the total physician's charge for the visit.

DATE OF VISIT	TYPE OF PHYSICIAN	TOTAL PHYSICIAN'S CHARGE
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

88. In the past 3 months, have you had X-rays, lab tests or diagnostic tests performed (chest or pelvic X-rays, renograms, blood tests, EKGs, urine tests, needle biopsies, etc.)? Include all tests performed on an outpatient basis, but **DO NOT** include lab tests that were performed while you were in the hospital.

(CIRCLE ONE)

YES 01

NO 02 (SKIP TO Q.90)

89. For each X-ray, lab test or diagnostic test performed, please indicate on the table below the date of the test, type of test performed, and total charge for the test.

DATE OF TEST	TYPE OF TEST	TOTAL CHARGE

90. Finally, we are interested in the cost of all drugs which you are currently taking that are prescribed by your doctor. On the table below, please provide the name of each drug, the number of times that you have obtained this drug in the last 3 months, and the cost of refilling each prescription (Much of this information can be obtained from the labels on the drug bottles.)

NAME OF DRUG	NUMBER OF TIMES OBTAINED	COST OF EACH PRESCRIPTION

91. Have you had any difficulty paying for your immunosuppressive medications?

(CIRCLE ONE)

YES 01

NO 02 (SKIP TO Q.93)

92. Which of the following drugs have you had trouble paying for?

(CIRCLE ALL THAT APPLY)

A. CYCLOSPORINE 01

B. PREDNISONE (OR OTHER STEROID) 02

C. AZATHIOPRINE 03

D. OTHER (SPECIFY) 04

E. OTHER (SPECIFY) 05

93. Do you currently receive any assistance in paying for immunosuppressive drugs?

(CIRCLE ONE)

YES 01

NO, I PAY OUT-OF-POCKET 02 (SKIP TO Q.95)

94. From which of the following sources do you receive assistance in paying for your immunosuppressive drugs?

(CIRCLE ALL THAT APPLY)

A. PRIVATE INSURANCE 01

B. HOSPITAL OR TRANSPLANT CENTER 02

C. MEDICARE 03

D. MEDICAID 04

E. STATE KIDNEY PROGRAM 05

F. SPECIAL PATIENT FUND 06

G. OTHER (SPECIFY) 07

NOTTINGHAM HEALTH PROFILE

INTRODUCTION

The Nottingham Health Profile is an easily completed questionnaire intended to provide us with a general description of your current health status. This measure as well as other questions you have answered will give us an opportunity to determine how well the questions you answer relate to other measures of health status. Thus, several of the questions you will answer here are similar to others you have answered in this questionnaire.

Listed below are some problems people may have in their daily life. Look down the list and Circle 01 for any problem you have at the moment. Circle 02 for any problem that you do not have. If you are not sure whether to say yes or no, circle whichever answer you think is **MORE TRUE** at the moment.

	YES	NO
95. I'm tired all the time	01	02
96. I have pain at night	01	02
97. Things are getting me down	01	02
98. I have unbearable pain	01	02
99. I take tablets to help me sleep	01	02
100. I've forgotten what it's like to enjoy myself	01	02
101. I'm feeling on edge	01	02
102. I find it painful to change position	01	02
103. I feel lonely	01	02
104. I can only walk about indoors	01	02
105. I find it hard to bend	01	02
106. Everything is an effort	01	02
107. I'm waking up in the early hours of the morning	01	02
108. I'm unable to walk at all	01	02
109. I'm finding it hard to make contact with people	01	02
110. The days seem to drag	01	02
111. I have trouble getting up and down stairs or steps	01	02
112. I find it hard to reach for things	01	02

<p>REMEMBER. IF YOU ARE NOT SURE WHETHER TO ANSWER YES OR NO TO A PROBLEM. CIRCLE WHICHEVER ANSWER YOU THINK IS MORE TRUE AT THE MOMENT.</p>
--

	YES	NO
113. I'm in pain when I walk	01	02
114. I lose my temper easily these days	01	02
115. I feel there is nobody I am close to	01	02
116. I lie awake for most of the night	01	02
117. I feel as if I'm losing control	01	02
118. I'm in pain when I'm standing	01	02
119. I find it hard to dress myself	01	02
120. I soon run out of energy	01	02
121. I find it hard to stand for long (for example, at the kitchen sink, waiting for a bus)	01	02
122. I'm in constant pain	01	02
123. It takes me a long time to get to sleep	01	02
124. I feel I am a burden to people	01	02
125. Worry is keeping me awake at night	01	02
126. I feel life is not worth living	01	02
127. I sleep badly at night	01	02
128. I'm finding it hard to get along with people	01	02
129. I need help to walk about outside (for example, a walking aid or someone to support me)	01	02
130. I'm in pain when going up and down stairs or steps	01	02
131. I wake up feeling depressed	01	02
132. I'm in pain when I'm sitting	01	02

IN THE LIST BELOW, CIRCLE 01 FOR EACH ACTIVITY IN YOUR
LIFE WHICH IS BEING AFFECTED BY YOUR STATE OF HEALTH.
CIRCLE 02 FOR EACH ACTIVITY WHICH IS NOT BEING
AFFECTED, OR WHICH DOES NOT APPLY TO YOU

Is your present state of health causing problems with your...

		YES	NO
133.	Job or work (that is, paid employment)	01	02
134.	Looking after the home (Examples: cleaning and cooking, repairs, odd jobs around the home)	01	02
135.	Social life (Examples: going out, seeing friends, going to a show)	01	02
136.	Home life (That is: relationships with other people in your home)	01	02
137.	Sex life	01	02
138.	Interests and hobbies (Examples: sports, arts and crafts, do-it-yourself, etc.,	01	02
139.	Vacation (Examples: summer and winter vacations, weekends away, etc.)	01	02

SICKNESS IMPACT PROFILE

INTRODUCTION

Transplant teams continue to concern themselves with the postoperative health status of transplant recipients. Researchers have developed many different health status measures. Depending upon how health status is defined, some of these measures are more extensive than others. The health status measure that follows, known as the Sickness Impact Profile, is among the most detailed available and is intended to measure the extent to which sickness has an impact on your ability to do certain activities. Some of the questions may seem quite similar to those you have just answered. However, it is important that we include them to maintain the standardized nature of the Sickness Impact Profile.

We realize that this questionnaire has already taken a considerable amount of your time and effort. You may want to stop at this point and complete this final part of the questionnaire tomorrow. It will probably take about 20 minutes to complete this part of the questionnaire. Instructions for the Sickness Impact Profile are on the following pages.

INSTRUCTIONS

PLEASE READ THE FOLLOWING INTRODUCTION **BEFORE** YOU READ THE QUESTIONNAIRE. IT IS VERY IMPORTANT THAT EVERYONE COMPLETING THE QUESTIONNAIRE FOLLOWS THE SAME INSTRUCTIONS.

INTRODUCTION TO RESPONDENT

You have certain activities that you do in carrying on your life. Sometimes you do all of these activities. Other times, because of your state of health, you don't do these activities in the usual way: you may cut some out; you may do some for shorter lengths of time; you may do some in different ways. These changes in your activities might be recent or longstanding. We are interested in learning about any changes that describe you today and are related to your state of health.

The questionnaire booklet lists statements that people have told us describe them when they are not completely well. Whether or not you consider yourself sick, there may be some statements that will stand out because they describe you today and are related to your state of health. As you read the questionnaire, think of yourself today. When you read a statement that you are sure describes you and is related to your health, place a check on the line to the right of the statement. For example:

I am not driving my car

☒ (026-031)

If you have not been driving for some time because of your health, and are still not driving today, you should respond to this statement.

On the other hand, if you never drive or are not driving today because your car is being repaired, the statement, "I am not driving my car" is not related to your health and you should not check it. If you simply are driving less, or are driving short distances, and feel that the statement only partially describes you, do not check it. In all of these cases you would leave the line to the right of the statement blank. For example:

I am not driving my car

☐ (026-031)

Remember that we want you to check this statement only if you are sure it describes you today and is related to your state of health.

Read the introduction to each group of statements and then consider the statements in the order listed. While some of the statements may not apply to you, we ask that you please read all of them. Check those that describe you as you go along. Some of the statements will differ only in a few words, so please read each one carefully. While you may go back to change a response, your first answer is usually the best. Please do not read ahead in the booklet.

Once you have started the questionnaire, it is very important that you complete it within one day (24 hours).

If you find it hard to keep your mind on the statements, take a short break and then continue. When you have read all of the statements on a page, put a check in the BOX in the lower right-hand corner. If you have any questions, please refer back to these instructions.

Please do not discuss the statements with anyone, including family members, while doing the questionnaire.

Now turn to the questionnaire booklet and read the statements. Remember we are interested in the recent or longstanding changes in your activities that are related to your health.

PLEASE RESPOND TO **ONLY** THOSE STATEMENTS THAT YOU ARE **SURE** DESCRIBE YOU TODAY AND ARE RELATED TO YOUR STATE OF HEALTH.

140. I spend much of the day lying down in order to rest _____ (083)
141. I sit during much of the day _____ (049)
142. I am sleeping or dozing most of the time—day and night _____ (104)
143. I lie down more often during the day in order to rest _____ (158)
144. I sit around half-asleep _____ (084)
145. I sleep less at night, for example, wake up too early,
don't fall asleep for a long time, awaken frequently _____ (061)
146. I sleep or nap more during the day _____ (060)

CHECK HERE WHEN YOU HAVE READ ALL STATEMENTS ON THIS PAGE

☐

PLEASE RESPOND TO **ONLY** THOSE STATEMENTS THAT YOU ARE **SURE** DESCRIBE YOU TODAY AND ARE RELATED TO YOUR STATE OF HEALTH.

- | | | |
|------|---|-------------|
| 147. | I say how bad or useless I am, for example, that I am a burden on others | _____ (087) |
| 148. | I laugh or cry suddenly | _____ (068) |
| 149. | I often moan and groan in pain or discomfort | _____ (069) |
| 150. | I have attempted suicide | _____ (132) |
| 151. | I act nervous or restless | _____ (046) |
| 152. | I keep rubbing or holding areas of my body that hurt or are uncomfortable | _____ (062) |
| 153. | I act irritable and impatient with myself, for example, talk badly about myself, swear at myself, blame myself for things that happen | _____ (078) |
| 154. | I talk about the future in a hopeless way | _____ (089) |
| 155. | I get sudden frights | _____ (074) |

CHECK HERE WHEN YOU HAVE READ ALL STATEMENTS ON THIS PAGE



PLEASE RESPOND TO **ONLY** THOSE STATEMENTS THAT YOU ARE **SURE** DESCRIBE YOU TODAY AND ARE RELATED TO YOUR STATE OF HEALTH.

- | | | |
|------|--|-------------|
| 156. | I make difficult moves with help, for example, getting into or out of cars, bathtubs | _____ (084) |
| 157. | I do not move into or out of bed or chair by myself but am moved by a person or mechanical aid | _____ (121) |
| 158. | I stand only for short periods of time | _____ (072) |
| 159. | I do not maintain balance | _____ (098) |
| 160. | I move my hands or fingers with some limitation or difficulty | _____ (064) |
| 161. | I stand up only with someone's help | _____ (100) |
| 162. | I kneel, stoop, or bend down only by holding on to something | _____ (064) |
| 163. | I am in a restricted position all the time | _____ (125) |
| 164. | I am very clumsy in body movements | _____ (068) |
| 165. | I get in and out of bed or chairs by grasping something for support or using a cane or walker | _____ (082) |
| 166. | I stay lying down most of the time | _____ (113) |
| 167. | I change position frequently | _____ (030) |
| 168. | I hold on to something to move myself around in bed | _____ (086) |
| 169. | I do not bathe myself completely, for example, require assistance with bathing | _____ (089) |
| 170. | I do not bathe myself at all, but am bathed by someone else | _____ (115) |
| 171. | I use bedpan with assistance | _____ (114) |
| 172. | I have trouble getting shoes, socks, or stockings on | _____ (057) |
| 173. | I do not have control of my bladder | _____ (124) |

174. I do not fasten my clothing, for example, require assistance with buttons, zippers, shoelaces _____ (074)
175. I spend most of the time partly undressed or in pajamas _____ (074)
176. I do not have control of my bowels _____ (128)
177. I dress myself, but do so very slowly _____ (043)
178. I get dressed only with someone's help _____ (088)

CHECK HERE WHEN YOU HAVE READ ALL STATEMENTS ON THIS PAGE

☐

THIS GROUP OF STATEMENTS HAS TO DO WITH ANY WORK YOU USUALLY DO IN CARING FOR YOUR HOME OR YARD, CONSIDERING JUST THOSE THINGS THAT YOU DO. PLEASE RESPOND TO ONLY THOSE STATEMENTS THAT YOU ARE **SURE** DESCRIBE YOU TODAY AND ARE RELATED TO YOUR STATE OF HEALTH.

- | | | |
|------|---|-------------|
| 179. | I do work around the house only for short periods of time or rest often | _____ (054) |
| 180. | I am doing <u>less</u> of the regular daily work around the house than I would usually do | _____ (044) |
| 181. | I am not doing <u>any</u> of the regular daily work around the house that I would usually do | _____ (086) |
| 182. | I am not doing <u>any</u> of the maintenance or repair work that I would usually do in my home or yard | _____ (062) |
| 183. | I am not doing <u>any</u> of the shopping that I would usually do | _____ (071) |
| 184. | I am not doing <u>any</u> of the house cleaning that I would usually do | _____ (077) |
| 185. | I have difficulty doing handwork, for example, turning faucets, using kitchen gadgets, sewing, carpentry | _____ (069) |
| 186. | I am not doing <u>any</u> of the clothes washing that I would usually do | _____ (077) |
| 187. | I am not doing heavy work around the house | _____ (044) |
| 188. | I have given up taking care of personal or household business affairs, for example, paying bills, banking, working on budget. | _____ (064) |

CHECK HERE WHEN YOU HAVE READ ALL STATEMENTS ON THIS PAGE

☐

PLEASE RESPOND TO ONLY THOSE STATEMENTS THAT YOU ARE SURE DESCRIBE YOU TODAY AND ARE RELATED TO YOUR STATE OF HEALTH.

- | | | |
|------|--|-------------|
| 189. | I am getting around only within one building | _____ (086) |
| 190. | I stay within one room | _____ (106) |
| 191. | I am staying in bed more | _____ (081) |
| 192. | I am staying in bed most of the time | _____ (109) |
| 193. | I am not now using public transportation | _____ (041) |
| 194. | I stay home most of the time | _____ (056) |
| 195. | I am only going to places with restrooms nearby | _____ (056) |
| 196. | I am not going into town | _____ (048) |
| 197. | I stay away from home only for brief periods of time | _____ (054) |
| 198. | I do not get around in the dark or in unlit places
without someone's help | _____ (072) |

CHECK HERE WHEN YOU HAVE READ ALL STATEMENTS ON THIS PAGE

☐

PLEASE RESPOND TO **ONLY** THOSE STATEMENTS THAT YOU ARE **SURE** DESCRIBE YOU TODAY AND ARE RELATED TO YOUR STATE OF HEALTH.

- | | | |
|------|--|-------------|
| 199. | I am going out less to visit people | _____ (044) |
| 200. | I am not going out to visit people at all | _____ (101) |
| 201. | I show less interest in other people's problems, for example, don't listen when they tell me about their problems, don't offer to help | _____ (067) |
| 202. | I often act irritable toward those around me, for example, snap at people, give sharp answers, criticize easily | _____ (084) |
| 203. | I show less affection | _____ (052) |
| 204. | I am doing fewer social activities with groups of people | _____ (036) |
| 205. | I am cutting down the length of visits with friends | _____ (043) |
| 206. | I am avoiding social visits from others | _____ (080) |
| 207. | My sexual activity is decreased | _____ (051) |
| 208. | I often express concern over what might be happening to my health | _____ (052) |
| 209. | I talk less with those around me | _____ (056) |
| 210. | I make many demands, for example, insist that people do things for me, tell them how to do things | _____ (088) |
| 211. | I stay alone much of the time | _____ (086) |
| 212. | I act disagreeable to family members, for example I act spiteful, I am stubborn | _____ (038) |
| 213. | I have frequent outbursts of anger at family members, for example, strike at them, scream, throw things at them | _____ (119) |
| 214. | I isolate myself as much as I can from the rest of the family | _____ (102) |

215. I am paying less attention to the children _____ (064)
216. I refuse contact with family members, for example,
turn away from them _____ (115)
217. I am not doing the things I usually do to take care
of my children or family _____ (079)
218. I am not joking with family members as I usually do _____ (035)

CHECK HERE WHEN YOU HAVE READ ALL STATEMENTS ON THIS PAGE

☐

PLEASE RESPOND TO **ONLY** THOSE STATEMENTS THAT YOU ARE **SURE** DESCRIBE YOU TODAY AND ARE RELATED TO YOUR STATE OF HEALTH.

- | | | |
|------|---|-------------|
| 219. | I walk shorter distances or stop to rest often | _____ (048) |
| 220. | I do not walk up or down hills | _____ (056) |
| 221. | I use stairs only with mechanical support, for example, handrail, cane, crutches | _____ (067) |
| 222. | I walk up or down stairs only with assistance from someone else | _____ (076) |
| 223. | I get around in a wheelchair | _____ (096) |
| 224. | I do not walk at all | _____ (105) |
| 225. | I walk by myself but with some difficulty, for example, limp, wobble, stumble, have stiff leg | _____ (055) |
| 226. | I walk only with help from someone | _____ (088) |
| 227. | I go up and down stairs more slowly, for example, one step at a time, stop often | _____ (054) |
| 228. | I do not use stairs at all | _____ (083) |
| 229. | I get around only by using a walker, crutches, cane, walls, or furniture | _____ (079) |
| 230. | I walk more slowly | _____ (035) |

CHECK HERE WHEN YOU HAVE READ ALL STATEMENTS ON THIS PAGE

☐

PLEASE RESPOND TO **ONLY** THOSE STATEMENTS THAT YOU ARE **SURE** DESCRIBE YOU TODAY AND ARE RELATED TO YOUR STATE OF HEALTH.

231. I am confused and start several actions at a time _____ (090)
232. I have more minor accidents, for example, drop things, trip and fall, bump into things _____ (075)
233. I react slowly to things that are said or done _____ (059)
234. I do not finish things I start _____ (067)
235. I have difficulty reasoning and solving problems, for example, making plans, making decisions, learning new things _____ (084)
236. I sometimes behave as if I were confused or disoriented in place or time, for example, where I am, who is around, directions, what day it is _____ (113)
237. I forget a lot, for example, things that happened recently, where I put things, appointments _____ (078)
238. I do not keep my attention on any activity for long _____ (067)
239. I make more mistakes than usual _____ (064)
240. I have difficulty doing activities involving concentration and thinking _____ (080)

CHECK HERE WHEN YOU HAVE READ ALL STATEMENTS ON THIS PAGE

☐

PLEASE RESPOND TO **ONLY** THOSE STATEMENTS THAT YOU ARE **SURE** DESCRIBE YOU TODAY AND ARE RELATED TO YOUR STATE OF HEALTH.

241. I am having trouble writing or typing _____ (070)
242. I communicate mostly by gestures, for example,
moving head, pointing, sign language _____ (102)
243. My speech is understood only by a few people
who know me well _____ (093)
244. I often lose control of my voice when I talk, for
example, my voice gets louder or softer, trembles,
changes unexpectedly _____ (083)
245. I don't write except to sign my name _____ (063)
246. I carry on a conversation only when very close
to the other person or looking at him _____ (067)
247. I have difficulty speaking, for example, get stuck,
stutter, stammer, slur my words _____ (076)
248. I am understood with difficulty _____ (087)
249. I do not speak clearly when I am under stress _____ (064)

CHECK HERE WHEN YOU HAVE READ ALL STATEMENTS ON THIS PAGE



THE NEXT GROUP OF STATEMENTS HAS TO DO WITH ANY WORK YOU USUALLY DO OTHER THAN MANAGING YOUR HOME. BY THIS WE MEAN ANYTHING THAT YOU REGARD AS WORK THAT YOU DO ON A REGULAR BASIS.

250. DO YOU USUALLY DO WORK OTHER THAN
MANAGING YOUR HOME?

YES

NO

→ IF YOU ANSWERED YES, GO ON TO THE NEXT PAGE

→ IF YOU ANSWERED NO:

251. ARE YOU RETIRED?

YES

NO

252. IF YOU ARE RETIRED, WAS YOUR
RETIREMENT RELATED TO YOUR HEALTH?

YES

NO

253. IF YOU ARE NOT RETIRED, BUT ARE
NOT WORKING, IS THIS RELATED TO
YOUR HEALTH?

YES

NO

→ NOW SKIP THE NEXT PAGE

IF YOU ARE NOT WORKING AND IT IS NOT BECAUSE OF
YOUR HEALTH, PLEASE SKIP THIS PAGE

NOW CONSIDER THE WORK YOU DO AND RESPOND TO ONLY THOSE STATEMENTS THAT YOU ARE SURE DESCRIBE YOU TODAY AND ARE RELATED TO YOUR STATE OF HEALTH. (IF TODAY IS A SATURDAY OR SUNDAY OR SOME OTHER DAY THAT YOU WOULD USUALLY HAVE OFF, PLEASE RESPOND AS IF TODAY WERE A WORKING DAY.)

254. I am not working at all _____ (361)

(IF YOU CHECKED THIS STATEMENT, SKIP TO THE NEXT PAGE)

255. I am doing part of my job at home _____ (037)

256. I am not accomplishing as much as usual at work _____ (055)

257. I often act irritable toward my work associates,
for example, snap at them, give sharp answers,
criticize easily _____ (080)

258. I am working shorter hours _____ (043)

259. I am doing only light work _____ (050)

260. I work only for short periods of time or take
frequent rests _____ (021)

261. I am working at my usual job but with some changes,
for example, using different tools or special aids,
trading some tasks with other workers _____ (034)

262. I do not do my job as carefully and accurately as usual _____ (062)

CHECK HERE WHEN YOU HAVE READ ALL STATEMENTS ON THIS PAGE



THIS GROUP OF STATEMENTS HAS TO DO WITH ACTIVITIES YOU USUALLY DO IN YOUR FREE TIME. THESE ACTIVITIES ARE THINGS THAT YOU MIGHT DO FOR RELAXATION, TO PASS THE TIME, OR FOR ENTERTAINMENT. PLEASE RESPOND TO **ONLY** THOSE STATEMENTS THAT YOU ARE SURE DESCRIBE YOU TODAY AND ARE RELATED TO YOUR STATE OF HEALTH.

263. I do my hobbies and recreation for shorter periods of time _____ (039)
264. I am going out for entertainment less often _____ (036)
265. I am cutting down on some of my usual inactive recreation and pastimes, for example, watching TV, playing cards, reading _____ (059)
266. I am not doing any of my usual inactive recreation and pastimes, for example, watching TV, playing cards, reading _____ (084)
267. I am doing more inactive pastimes in place of my other usual activities _____ (051)
268. I am doing fewer community activities _____ (033)
269. I am cutting down on some of my usual physical recreation or activities _____ (043)
270. I am not doing any of my usual physical recreation or activities _____ (077)

CHECK HERE WHEN YOU HAVE READ ALL STATEMENTS ON THIS PAGE

☐

PLEASE RESPOND TO **ONLY** THOSE STATEMENTS THAT YOU ARE **SURE** DESCRIBE YOU TODAY AND ARE RELATED TO YOUR STATE OF HEALTH.

271. I am eating much less than usual _____ (037)
272. I feed myself but only by using specially prepared food or utensils _____ (077)
273. I am eating special or different food, for example, soft food, bland diet, low-salt, low-fat, low-sugar _____ (043)
274. I eat no food at all but am taking fluids _____ (104)
275. I just pick or nibble at my food _____ (059)
276. I am drinking less fluids _____ (036)
277. I feed myself with help from someone else _____ (099)
278. I do not feed myself at all, but must be fed _____ (117)
279. I am eating no food at all, nutrition is taken through tubes or intravenous fluids _____ (133)

CHECK HERE WHEN YOU HAVE READ ALL STATEMENTS ON THIS PAGE

☐

CONCLUSION OF THE QUESTIONNAIRE

We at the Battelle Human Affairs Research Centers very much appreciate the time and effort you have put into this questionnaire. The information you have provided is essential to meeting the objectives of the Renal Transplantation Study. If you have any comments regarding the study, please record them below.

This image shows a single sheet of white paper with horizontal blue or grey ruling lines, typical of notebook paper. The lines are evenly spaced and run across the width of the page. There is no handwriting or other markings on the paper.

THANK YOU FOR YOUR COOPERATION

PLEASE RETURN THE COMPLETED QUESTIONNAIRE IN THE
ENCLOSED POSTAGE-PAID ENVELOPE



APPENDIX G

THE NATIONAL ORGAN TRANSPLANTATION ACT

Public Law 98-507
98th Congress

An Act

To provide for the establishment of the Task Force on Organ Transplantation and the Organ Procurement and Transplantation Network, to authorize financial assistance for organ procurement organizations, and for other purposes.

Oct. 19, 1984
[S. 2048]

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That this Act may be cited as the "National Organ Transplant Act".

National Organ
Transplant Act.
42 USC 201 note.
Health.

TITLE I—TASK FORCE ON ORGAN PROCUREMENT AND
TRANSPLANTATION

ESTABLISHMENT AND DUTIES OF TASK FORCE

SEC. 101. (a) Not later than ninety days after the date of the enactment of this Act, the Secretary of Health and Human Services (hereinafter in this title referred to as the "Secretary") shall establish a Task Force on Organ Transplantation (hereinafter in this title referred to as the "Task Force").

42 USC 273 note.

(b)(1) The Task Force shall—

(A) conduct comprehensive examinations of the medical, legal, ethical, economic, and social issues presented by human organ procurement and transplantation,

(B) prepare the assessment described in paragraph (2) and the report described in paragraph (3), and

(C) advise the Secretary with respect to the development of regulations for grants under section 371 of the Public Health Service Act.

Post, p. 2342.

(2) The Task Force shall make an assessment of immunosuppressive medications used to prevent organ rejection in transplant patients, including—

(A) an analysis of the safety, effectiveness, and costs (including cost-savings from improved success rates of transplantation) of different modalities of treatment;

(B) an analysis of the extent of insurance reimbursement for long-term immunosuppressive drug therapy for organ transplant patients by private insurers and the public sector;

(C) an identification of problems that patients encounter in obtaining immunosuppressive medications; and

(D) an analysis of the comparative advantages of grants, coverage under existing Federal programs, or other means to assure that individuals who need such medications can obtain them.

(3) The Task Force shall prepare a report which shall include—

Report.

(A) an assessment of public and private efforts to procure human organs for transplantation and an identification of factors that diminish the number of organs available for transplantation;

(B) an assessment of problems in coordinating the procurement of viable human organs including skin and bone;

(C) recommendations for the education and training of health professionals, including physicians, nurses, and hospital and emergency care personnel, with respect to organ procurement;

(D) recommendations for the education of the general public, the clergy, law enforcement officers, members of local fire departments, and other agencies and individuals that may be instrumental in effecting organ procurement;

(E) recommendations for assuring equitable access by patients to organ transplantation and for assuring the equitable allocation of donated organs among transplant centers and among patients medically qualified for an organ transplant;

(F) an identification of barriers to the donation of organs to patients (with special emphasis upon pediatric patients), including an assessment of—

(i) barriers to the improved identification of organ donors and their families and organ recipients;

(ii) the number of potential organ donors and their geographical distribution;

(iii) current health care services provided for patients who need organ transplantation and organ procurement procedures, systems, and programs which affect such patients;

(iv) cultural factors affecting the family with respect to the donation of the organs; and

(v) ethical and economic issues relating to organ transplantation needed by chronically ill patients;

(G) recommendations for the conduct and coordination of continuing research concerning all aspects of the transplantation of organs;

(H) an analysis of the factors involved in insurance reimbursement for transplant procedures by private insurers and the public sector;

(I) an analysis of the manner in which organ transplantation technology is diffused among and adopted by qualified medical centers, including a specification of the number and geographical distribution of qualified medical centers using such technology and an assessment of whether the number of centers using such technology is sufficient or excessive and of whether the public has sufficient access to medical procedures using such technology; and

(J) an assessment of the feasibility of establishing, and of the likely effectiveness of, a national registry of human organ donors.

MEMBERSHIP

42 USC 273 note.

SEC. 102. (a) The Task Force shall be composed of twenty-five members as follows:

(1) Twenty-one members shall be appointed by the Secretary of which:

(A) nine members shall be physicians or scientists who are eminent in the various medical and scientific specialties related to human organ transplantation;

(B) three members shall be individuals who are not physicians and who represent the field of human organ procurement;

(C) four members shall be individuals who are not physicians and who as a group have expertise in the fields of law,

theology, ethics, health care financing, and the social and behavioral sciences;

(D) three members shall be individuals who are not physicians or scientists and who are members of the general public; and

(E) two members shall be individuals who represent private health insurers or self-insurers.

(2) The Surgeon General of the United States, the Director of the National Institutes of Health, the Commissioner of the Food and Drug Administration, and the Administrator of the Health Care Financing Administration shall be ex officio members.

(b) No individual who is a full-time officer or employee of the United States may be appointed under subsection (a)(1) to the Task Force. A vacancy in the Task Force shall be filled in the manner in which the original appointment was made. A vacancy in the Task Force shall not affect its powers.

(c) Members shall be appointed for the life of the Task Force.

(d) The Task Force shall select a Chairman from among its members who are appointed under subsection (a)(1).

(e) Thirteen members of the Task Force shall constitute a quorum, but a lesser number may hold hearings.

(f) The Task Force shall hold its first meeting on a date specified by the Secretary which is not later than thirty days after the date on which the Secretary establishes the Task Force under section 101. Thereafter, the Task Force shall meet at the call of the Chairman or a majority of its members, but shall meet at least three times during the life of the Task Force.

(g)(1) Each member of the Task Force who is not an officer or employee of the United States shall be compensated at a rate equal to the daily equivalent of the annual rate of basic pay in effect for grade GS-18 of the General Schedule under section 5332 of title 5, United States Code, for each day (including traveltime) during which such member is engaged in the actual performance of duties as a member of the Task Force. Each member of the Task Force who is an officer or employee of the United States shall receive no additional compensation.

(2) While away from their homes or regular places of business in the performance of duties for the Task Force, all members of the Task Force shall be allowed travel expenses, including per diem in lieu of subsistence, at rates authorized for employees of agencies under sections 5702 and 5703 of title 5, United States Code.

SUPPORT FOR THE TASK FORCE

SEC. 103. (a) Upon request of the Task Force, the head of any Federal agency is authorized to detail, on a reimbursable basis, any of the personnel of such agency to the Task Force to assist the Task Force in carrying out its duties under this Act. 42 USC 273 note.

(b) The Secretary shall provide the Task Force with such administrative and support services as the Task Force may require to carry out its duties.

REPORT

SEC. 104. (a) The Task Force may transmit to the Secretary, the Committee on Labor and Human Resources of the Senate, and the 42 USC 273 note.

- Committee on Energy and Commerce of the House of Representatives such interim reports as the Task Force considers appropriate.
- Report. (b) Not later than 7 months after the date on which the Task Force is established by the Secretary under section 101, the Task Force shall transmit a report to the Secretary, the Committee on Labor and Human Resources of the Senate, and the Committee on Energy and Commerce of the House of Representatives on its assessment under section 101(b)(2) of immunosuppressive medications used to prevent organ rejection.
- Report. (c) Not later than twelve months after the date on which the Task Force is established by the Secretary under section 101, the Task Force shall transmit a final report to the Secretary, the Committee on Labor and Human Resources of the Senate, and the Committee on Energy and Commerce of the House of Representatives. The final report of the Task Force shall include—
- (1) a description of any findings and conclusions of the Task Force made pursuant to any examination conducted under section 101(b)(1)(A),
 - (2) the matters specified in section 101(b)(3), and
 - (3) such recommendations as the Task Force considers appropriate.

TERMINATION

- 42 USC 273 note. SEC. 105. The Task Force shall terminate three months after the date on which the Task Force transmits the report required by section 104(c).

TITLE II—ORGAN PROCUREMENT ACTIVITIES

SEC. 201. Part H of title III of the Public Health Service Act is amended to read as follows:

"PART H—ORGAN TRANSPLANTS

"ASSISTANCE FOR ORGAN PROCUREMENT ORGANIZATIONS

- Grants.
42 USC 273. "SEC. 371. (a)(1) The Secretary may make grants for the planning of qualified organ procurement organizations described in subsection (b).
- "(2) The Secretary may make grants for the establishment, initial operation, and expansion of qualified organ procurement organizations described in subsection (b).
- "(3) In making grants under paragraphs (1) and (2), the Secretary shall—
- "(A) take into consideration any recommendations made by the Task Force on Organ Transplantation established under section 101 of the National Organ Transplant Act, and
- "(B) give special consideration to applications which cover geographical areas which are not adequately served by organ procurement organizations.
- "(b)(1) A qualified organ procurement organization for which grants may be made under subsection (a) is an organization which, as determined by the Secretary, will carry out the functions described in paragraph (2) and—
- "(A) is a nonprofit entity,
- Ante, p. 2339.

"(B) has accounting and other fiscal procedures (as specified by the Secretary) necessary to assure the fiscal stability of the organization,

"(C) has an agreement with the Secretary to be reimbursed under title XVIII of the Social Security Act for the procurement of kidneys, 42 USC 1395.

"(D) has procedures to obtain payment for non-renal organs provided to transplant centers,

"(E) has a defined service area which is a geographical area of sufficient size which (unless the service area comprises an entire State) will include at least fifty potential organ donors each year and which either includes an entire standard metropolitan statistical area (as specified by the Office of Management and Budget) or does not include any part of such an area,

"(F) has a director and such other staff, including the organ donation coordinators and organ procurement specialists necessary to effectively obtain organs from donors in its service area, and

"(G) has a board of directors or an advisory board which—

"(i) is composed of—

"(I) members who represent hospital administrators, intensive care or emergency room personnel, tissue banks, and voluntary health associations in its service area,

"(II) members who represent the public residing in such area,

"(III) a physician with knowledge, experience, or skill in the field of histocompatibility,

"(IV) a physician with knowledge or skill in the field of neurology, and

"(V) from each transplant center in its service area which has arrangements described in paragraph (2)(G) with the organization, a member who is a surgeon who has practicing privileges in such center and who performs organ transplant surgery,

"(ii) has the authority to recommend policies for the procurement of organs and the other functions described in paragraph (2), and

"(iii) has no authority over any other activity of the organization.

"(2) An organ procurement organization shall—

"(A) have effective agreements, to identify potential organ donors, with a substantial majority of the hospitals and other health care entities in its service area which have facilities for organ donations,

"(B) conduct and participate in systematic efforts, including professional education, to acquire all useable organs from potential donors,

"(C) arrange for the acquisition and preservation of donated organs and provide quality standards for the acquisition of organs which are consistent with the standards adopted by the Organ Procurement and Transplantation Network under section 372(b)(2)(D),

"(D) arrange for the appropriate tissue typing of donated organs,

"(E) have a system to allocate donated organs among transplant centers and patients according to established medical criteria,

"(F) provide or arrange for the transportation of donated organs to transplant centers,

"(G) have arrangements to coordinate its activities with transplant centers in its service area,

"(H) participate in the Organ Procurement Transplantation Network established under section 372,

"(I) have arrangements to cooperate with tissue banks for the retrieval, processing, preservation, storage, and distribution of tissues as may be appropriate to assure that all useable tissues are obtained from potential donors, and

"(J) evaluate annually the effectiveness of the organization in acquiring potentially available organs.

Appropriation
authorization.

"(c) For grants under subsection (a) there are authorized to be appropriated \$5,000,000 for fiscal year 1985, \$8,000,000 for fiscal year 1986, and \$12,000,000 for fiscal year 1987.

"ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK

42 USC 274.

"SEC. 372. (a) The Secretary shall by contract provide for the establishment and operation of an Organ Procurement and Transplantation Network which meets the requirements of subsection (b). The amount provided under such contract in any fiscal year may not exceed \$2,000,000. Funds for such contracts shall be made available from funds available to the Public Health Service from appropriations for fiscal years beginning after fiscal year 1984.

"(b)(1) The Organ Procurement and Transplantation Network shall carry out the functions described in paragraph (2) and shall—

"(A) be a private nonprofit entity which is not engaged in any activity unrelated to organ procurement, and

"(B) have a board of directors which includes representatives of organ procurement organizations (including organizations which have received grants under section 371), transplant centers, voluntary health associations, and the general public.

"(2) The Organ Procurement and Transplantation Network shall—

"(A) establish in one location or through regional centers—

"(i) a national list of individuals who need organs, and

"(ii) a national system, through the use of computers and in accordance with established medical criteria, to match organs and individuals included in the list, especially individuals whose immune system makes it difficult for them to receive organs,

"(B) maintain a twenty-four-hour telephone service to facilitate matching organs with individuals included in the list,

"(C) assist organ procurement organizations in the distribution of organs which cannot be placed within the service areas of the organizations,

"(D) adopt and use standards of quality for the acquisition and transportation of donated organs,

"(E) prepare and distribute, on a regionalized basis, samples of blood sera from individuals who are included on the list and whose immune system makes it difficult for them to receive organs, in order to facilitate matching the compatibility of such individuals with organ donors,

"(F) coordinate, as appropriate, the transportation of organs from organ procurement organizations to transplant centers,

"(G) provide information to physicians and other health professionals regarding organ donation, and

"(H) collect, analyze, and publish data concerning organ donation and transplants.

"SCIENTIFIC REGISTRY

"SEC. 373. The Secretary shall, by grant or contract, develop and maintain a scientific registry of the recipients of organ transplants. The registry shall include such information respecting patients and transplant procedures as the Secretary deems necessary to an ongoing evaluation of the scientific and clinical status of organ transplantation. The Secretary shall prepare for inclusion in the report under section 376 an analysis of information derived from the registry.

42 USC 274a.

"GENERAL PROVISIONS RESPECTING GRANTS AND CONTRACTS

"SEC. 374. (a) No grant may be made under section 371 or 373 or contract entered into under section 372 or 373 unless an application therefor has been submitted to, and approved by, the Secretary. Such an application shall be in such form and shall be submitted in such manner as the Secretary shall by regulation prescribe.

Grants.
42 USC 274b.

"(b)(1) In considering applications for grants under section 371—

"(A) the Secretary shall give priority to any applicant which has a formal agreement of cooperation with all transplant centers in its proposed service area,

"(B) the Secretary shall give special consideration to organizations which met the requirements of section 371(b) before the date of the enactment of this section, and

"(C) the Secretary shall not discriminate against an applicant solely because it provides health care services other than those related to organ procurement.

The Secretary may not make a grant for more than one organ procurement organization which serve the same service area.

Prohibition.

"(2) A grant for planning under section 371 may be made for one year with respect to any organ procurement organization and may not exceed \$100,000.

"(3) Grants under section 371 for the establishment, initial operation, or expansion of organ procurement organizations may be made for two years. No such grant may exceed \$500,000 for any year and no organ procurement organization may receive more than \$800,000 for initial operation or expansion.

"(c)(1) The Secretary shall determine the amount of a grant made under section 371 or 373. Payments under such grants may be made in advance on the basis of estimates or by the way of reimbursement, with necessary adjustments on account of underpayments or overpayments, and in such installments and on such terms and conditions as the Secretary finds necessary to carry out the purposes of such grants.

"(2)(A) Each recipient of a grant under section 371 or 373 shall keep such records as the Secretary shall prescribe, including records which fully disclose the amount and disposition by such recipient of the proceeds of such grant, the total cost of the undertaking in connection with which such grant was made, and the amount of that

Records.

- portion of the cost of the undertaking supplied by other sources, and such other records as will facilitate an effective audit.
- Audit. "(B) The Secretary and the Comptroller General of the United States, or any of their duly authorized representatives, shall have access for the purpose of audit and examination to any books, documents, papers, and records of the recipient of a grant under section 371 or 373 that are pertinent to such grant.
- "(d) For purposes of this part:
- "(1) The term 'transplant center' means a health care facility in which transplants of organs are performed.
- "(2) The term 'organ' means the human kidney, liver, heart, lung, pancreas, and any other human organ (other than corneas and eyes) specified by the Secretary by regulation and for purposes of section 373, such term includes bone marrow.

"ADMINISTRATION

- 42 USC 274c. "SEC. 375. The Secretary shall, during fiscal years 1985, 1986, 1987, and 1988, designate and maintain an identifiable administrative unit in the Public Health Service to—
- 42 USC 1395. "(1) administer this part and coordinate with the organ procurement activities under title XVIII of the Social Security Act,
- Public "(2) conduct a program of public information to inform the public of the need for organ donations,
- information. "(3) provide technical assistance to organ procurement organizations receiving funds under section 371, the Organ Procurement and Transplantation Network established under section 372, and other entities in the health care system involved in organ donations, procurement, and transplants, and
- Report. "(4) one year after the date on which the Task Force on Organ Transplantation transmits its final report under section 104(c) of the National Organ Transplant Act, and annually thereafter through fiscal year 1988, submit to Congress an annual report on the status of organ donation and coordination services and include in the report an analysis of the efficiency and effectiveness of the procurement and allocation of organs and a description of problems encountered in the procurement and allocation of organs.

"REPORT

- 42 USC 274d. "SEC. 376. The Secretary shall annually publish a report on the scientific and clinical status of organ transplantation. The Secretary shall consult with the Director of the National Institutes of Health and the Commissioner of the Food and Drug Administration in the preparation of the report."

TITLE III—PROHIBITION OF ORGAN PURCHASES

- Penalties. SEC. 301. (a) It shall be unlawful for any person to knowingly 42 USC 274e. acquire, receive, or otherwise transfer any human organ for valuable consideration for use in human transplantation if the transfer affects interstate commerce.
- (b) Any person who violates subsection (a) shall be fined not more than \$50,000 or imprisoned not more than five years, or both.
- (c) For purposes of subsection (a):
- (1) The term "human organ" means the human kidney, liver, heart, lung, pancreas, bone marrow, cornea, eye, bone, and skin,

and any other human organ specified by the Secretary of Health and Human Services by regulation.

(2) The term "valuable consideration" does not include the reasonable payments associated with the removal, transportation, implantation, processing, preservation, quality control, and storage of a human organ or the expenses of travel, housing, and lost wages incurred by the donor of a human organ in connection with the donation of the organ.

(3) The term "interstate commerce" has the meaning prescribed for it by section 201(b) of the Federal Food, Drug and Cosmetic Act.

21 USC 321.

TITLE IV—MISCELLANEOUS

BONE MARROW REGISTRY DEMONSTRATION AND STUDY

SEC. 401. (a) Not later than nine months after the date of enactment of this Act, the Secretary of Health and Human Services shall hold a conference on the feasibility of establishing and the effectiveness of a national registry of voluntary bone marrow donors.

42 USC 273 note.

(b) If the conference held under subsection (a) finds that it is feasible to establish a national registry of voluntary donors of bone marrow and that such a registry is likely to be effective in matching donors with recipients, the Secretary of Health and Human Services, acting through the Assistant Secretary for Health, shall, for purposes of the study under subsection (c), establish a registry of voluntary donors of bone marrow. The Secretary shall assure that—

(1) donors of bone marrow listed in the registry have given an informed consent to the donation of the bone marrow; and

(2) the names of the donors in the registry are kept confidential and access to the names and any other information in the registry is restricted to personnel who need the information to maintain and implement the registry, except that access to such other information shall be provided for purposes of the study under subsection (c).

If the conference held under subsection (a) makes the finding described in this subsection, the Secretary shall establish the registry not later than six months after the completion of the conference.

(c) The Secretary of Health and Human Services, acting through the Assistant Secretary for Health, shall study the establishment and implementation of the registry under subsection (b) to identify the issues presented by the establishment of such a registry, to evaluate participation of bone marrow donors, to assess the imple-

Report.

mentation of the informed consent and confidentiality requirements, and to determine if the establishment of a permanent bone marrow registry is needed and appropriate. The Secretary shall report the results of the study to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate not later than two years after the date the registry is established under subsection (b).

Approved October 19, 1984.

LEGISLATIVE HISTORY—S. 2048 (H.R. 5580) (H.R. 4080):

HOUSE REPORTS: No. 98-575, Pt. 1, accompanying H.R. 4080 (Comm. on Energy and Commerce), No. 98-769 accompanying H.R. 5580 (Comm. on Energy and Commerce), and No. 98-1127 (Comm. of Conference).

SENATE REPORT No. 98-382 (Comm. on Labor and Human Resources).

CONGRESSIONAL RECORD, Vol. 130 (1984):

Apr. 11, considered and passed Senate.

June 20, 21, H.R. 5580 considered and passed House; S. 2048, amended, passed in lieu.

Oct. 3, House agreed to conference report.

Oct. 4, Senate agreed to conference report.

WEEKLY COMPILATION OF PRESIDENTIAL DOCUMENTS, Vol. 20, No. 42 (1984):

Oct. 19, Presidential statement.

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APPENDIX H

FEDERAL REGISTER NOTICE OF JANUARY 19, 1988

duplication service alone, minus the charge for the first 100 reproduced pages. No charge shall be made for providing search for review services. Requests in this category must not be made for a commercial use.

(1) The term "representative of the news media" refers to any person actively gathering news for an entity that is organized and operated to publish or broadcast to the public.

(2) The term "news" means information that is about current events or that would be of current interest to the public.

(3) Examples of news media entities include television or radio stations broadcasting to the public at large, and publishers or periodicals which disseminate news and who make their products available for purchase or subscription by the general public.

(4) "Freelance" journalists may be regarded as working for a news organization if they can demonstrate a solid basis for expecting publication through that organization even though not actually employed by it.

(e) All other requesters—Fees for requesters who do not fit into any of the above categories shall be assessed for the full reasonable direct cost of searching for and duplicating documents that are responsive to a request, except that the first 100 pages of reproduction and the first two hours of search time shall be furnished without charge.

§ 51-7.14 Fee waivers and reductions.

The Committee will waive or reduce fees on requests for information if disclosure of the information is deemed to be in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the Government, and is not primarily in the commercial interest of the requester.

(a) In determining when fees shall be waived or reduced, the Committee will consider the following six factors:

(1) The subject of the request, i.e., whether the subject of the requested records concerns "the operations or activities of the government";

(2) The informative value of the information to be disclosed, i.e., whether the disclosure is "likely to contribute" to an understanding of Government operations or activities;

(3) The contribution to an understanding of the subject by the general public likely to result from disclosure, i.e., whether disclosure of the requested information will contribute to "public understanding";

(4) The significance of the contribution to public understanding, i.e., whether the disclosure is likely to

contribute "significantly" to public understanding of government operations or activities;

(5) The existence and magnitude of a commercial interest, i.e., whether the requester has a commercial interest that would be furthered by the requested disclosure; and, if so,

(6) The primary interest in disclosure, i.e., whether the magnitude of the identified commercial interest of the requester is sufficiently large, in comparison with the public interest in disclosure, that disclosure is "primarily in the commercial interest of the requester."

(b) The Committee may waive or reduce fees associated with a request for disclosure regardless of whether a waiver or reduction has been requested in the Committee determines that disclosure will primarily benefit the general public.

(c) Fees shall be waived, however, without discretion in all circumstances where the amount of the fee is \$20.00 or less.

§ 51-7.15 Collection of fees and charges.

(a) Except when prepayment is required, payments shall be collected to the fullest extent possible at the time the requested materials are furnished. Payments shall be made by requesters within 30 days of the date of the billing.

(b) Payments shall be made by check, draft, or money order made payable to the Treasury of the United States.

(c) In instances where a requester has previously failed to pay a fee, the Committee may require the requester to pay the full amount owed, plus any applicable interest as provided below, as well as the full estimated fee associated with any new request before it begins to process the new or subsequent request.

(d) On requests that result in fees being assessed, interest will be charged on an unpaid bill starting on the 31st day following the day on which the billing was sent. Interest will be at the rate prescribed in section 3717 of Title 31 U.S.C. and will accrue from the date of the billing.

(e) In attempting to collect fees levied under FOIA, the Committee will abide by the provisions of the Debt Collection Act of 1982 (Pub. L. 97-365) in disclosing information to consumer reporting agencies and in the use of collection agencies, where appropriate, to encourage payment.

§ 51-7.16 Preservation of records.

The Committee shall preserve all correspondence relating to the requests it receives under this part, and all records processed pursuant to such

requests, until such time as the destruction of such correspondence and records is authorized pursuant to Title 44 of the United States Code, and to the General Records Schedule. Records shall not be destroyed while they are the subject of a pending request, appeal, or lawsuit under the Act.

C.W. Fletcher,

Executive Director.

[FR Doc. 88-778 Filed 1-15-88; 8:45 am]

BILLING CODE 5420-33-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Part 410

(BERC-424-P)

Medicare Program; Medicare Coverage of Immunosuppressive Drugs

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would implement section 9325(c) of Pub. L. 99-509, the Omnibus Budget Reconciliation Act of 1986, which provides Medicare coverage for immunosuppressive drugs furnished to an individual who receives an organ transplant for which Medicare payment is made, for a period of one year after the transplant procedure.

DATE: Comments will be considered if we receive them at the appropriate address, as provided below, no later than 5:00 p.m. on March 21, 1988.

ADDRESS: Mail comments to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: BERC-424-P, P.O. Box 26676, Baltimore, Maryland 21207.

If you prefer, you may deliver your comments to one of the following addresses:

Room 309-G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC, or,
Room 132, East High Rise Building, 6325 Security Boulevard, Baltimore, Maryland.

In commenting, please refer to file code BERC-424-P. Comments received timely will be available for public inspection as they are received, generally beginning approximately three weeks after publication of a document, in Room 309-G of the Department's offices at 200 Independence Avenue SW., Washington, DC, on Monday

through Friday of each week from 8:30 a.m. to 5:00 p.m. (phone: 202-245-7890).

FOR FURTHER INFORMATION CONTACT:
James Hannon (301) 597-1734.

SUPPLEMENTARY INFORMATION:

I. Background

Before enactment of section 9335(c) of Pub. L. 99-509, Medicare coverage of immunosuppressive drugs had been provided only when furnished in an institutional setting or as "incident to" a physician's professional service. While sections 1861(s)(2) (A) and (B) of the Social Security Act (the Act) provided Medicare Part B coverage for "services and supplies (including drugs and biologicals which cannot, as determined in accordance with regulations, be self-administered * * *", immunosuppressive drugs have not been covered by Medicare because they may be self-administered. Currently, regulations at 42 CFR 410.10 (b) and (c) provide that payment may be made for drugs and biologicals that can not be self-administered when furnished "incident to" a physician's professional service, and regulations at 42 CFR 410.29 exclude from Medicare Part B coverage any drug or biological that can be self-administered, except when furnished by a hospital as part of an outpatient diagnostic service.

The Task Force on Organ Transplantation, established by the National Organ Transplant Act (Pub. L. 96-507) recommended unequivocally that Federal funds be used to provide these drugs (Report to the Secretary and the Congress on Immunosuppressive Therapies, October 1985). It has been established that the use of cyclosporine has lessened the duration of hospitalization as well as the accumulated charges in the first six months after the transplant. Cyclosporine also controls or minimizes graft failure and reduces rates of complications.

Accordingly, in section 9335(c) of Pub. L. 99-509, Congress amended section 1861(s)(2) of the Act to provide Medicare coverage of immunosuppressive drugs, furnished to an individual who receives an organ transplant for which Medicare payment is made, within one year after the date of the transplant procedure. Coverage of those drugs is available under Medicare Part B for immunosuppressive drugs furnished on or after January 1, 1987. To implement the new amendment HCFA issued manual instructions to its Medicare contractors in April 1987.

II. Proposed Policy for Coverage of Immunosuppressive Drugs

We are proposing to interpret the statutory phrase, "within one year after the date of the transplant procedure," to mean 365 days from the day on which an inpatient is discharged from the hospital. We believe the term "transplant procedure" can be interpreted to mean something broader than just the operation itself, and for the reasons set forth below, we propose to consider the procedure to end at the date of discharge. If the date of operation is used instead of the date of discharge, the immunosuppressive drug benefit would vary from one Medicare beneficiary to another, depending upon the patient's post-operative recovery period while an inpatient. For example, if one patient's hospital stay was 30 days longer than another patient's, the patient would receive less coverage under Part B. Further, the Conference Report accompanying Pub. L. 99-509 (H.R. Rept. 99-1012, page 337) indicates that Congress was aware that immunosuppressive drugs are already covered while a beneficiary is in the hospital. Nonetheless, Congress added this coverage by amending section 1861(s)(2) of the Act, which is a listing of "medical and other health services" covered under Part B of Medicare. By amending this section, Congress made immunosuppressive drugs a specific Part B benefit which extends explicitly for one year. Since inpatient immunosuppressive drugs are covered already under Part A, and since the date of discharge is later than the date of surgery, to use the actual transplant date would require us to either shorten the coverage period under Part B to less than one year or pay for inpatient hospital services with Part B funds. The former is inconsistent with Congressional intent. If we were to provide Part B benefits beginning at the time of the operation, we would have to adjust the DRG weights to exclude the costs of post-operative immunosuppressive drugs. This would be cumbersome. Further, it is administratively more difficult for the carrier to determine the date of the operation rather than the date of discharge.

We are proposing to provide coverage for those immunosuppressive drugs that have been specifically labeled as such and approved for marketing by the Food and Drug Administration (FDA). We would also provide coverage for other drugs that are used in conjunction with immunosuppressive drugs as part of a therapeutic regime reflected in FDA-approved labeling for

immunosuppressive drugs. By December 1986, the FDA had identified and approved for marketing only four specifically labeled immunosuppressive drugs to prevent rejection of a transplanted organ or tissue. They are:

- Sandimmune (cyclosporine), Sandoz Pharmaceutical;
- Imuran (azathioprine), Burroughs Wellcome;
- Atgam (antithymocyte globulin), Upjohn; and
- Orthoclone OKT3 (Muromonab-CD3), Ortho Pharmaceutical.

In addition, other drugs which are used in conjunction with immunosuppressives but not themselves labeled as immunosuppressive drugs include, for example, adrenal corticosteroids (prednisone) administered to patients receiving cyclosporine in accordance with FDA labeling of cyclosporine. (It should be noted that where any of the listed immunosuppressive drugs have to be administered by a physician, or as an incident to a physician's service, they could also have been covered and paid for by Medicare Part B prior to the enactment of Pub. L. 99-509 if it was furnished "incident to" the physician's professional service (see section 1861(s)(2) (A) and (B) of the Social Security Act)).

Payment is made on a reasonable cost basis if the beneficiary is the outpatient of a participating hospital. Payment will be made on a reasonable charge basis where the drugs are furnished by Part B suppliers or physicians.

In December 1985, manufacturers and the Red Book indicated that prices for the most commonly prescribed immunosuppressive drugs are as follows, although substantial discounts were available. Dosage is dependent on a number of medical factors as determined by the physician.

Sandimmune (cyclosporine), Sandoz Pharmaceutical:	
Amp. I.V. 250 mg., 5 ml., 10s ea. UD	\$144.60
Sol. Oral, 100 mg./ml., 50 ml., ea.	161.70
Imuran (azathioprine), Burroughs Wellcome:	
Vial, 100 mg., 20 ml. ea.	45.54
Tab. 50 mg., 100s ea.	59.16
Atgam, (antithymocyte globulin), Upjohn Amp. 50 mg./ml., 5 ml. ea.	
	87.50
Orthoclone OKT3 (muromonab- CD3) Ortho Amp. 5 mg./5 ml., 5 ml. ea.	
	300.00
Prednisone, Multiple Manufactur- ers Tab. 5 mg., 100s ea.	
	2.30

* This is a multiple source drug. We have given a mid-range price.

Generally beneficiaries will obtain immunosuppressive drugs from a hospital or community pharmacy or from their physician, for example, a transplant surgeon. However, some patients may obtain these drugs from mail-order pharmacies; they offer reduced prices which minimizes beneficiaries' coinsurance liability. In determining the reasonable charge for immunosuppressive drugs, the carriers will assure that their payments do not result in grossly excessive or grossly deficient charges taking these factors into account.

III. Proposed Revisions to Regulations Text

We propose to make the following revisions to the regulations text:

- We would revise § 410.10 to include immunosuppressive drugs in the term "medical and other health services".

- We would revise § 410.29 to exclude immunosuppressive drugs that would be covered as provided in § 410.65 from the term "any drug or biological that can be self-administered".

- We would add a new 42 CFR 410.65 to provide Medicare coverage of drugs used in immunosuppressive therapy that are furnished to an individual who receives an organ transplant for which Medicare payment is made, for a period of up to one year beginning with the date of discharge from the inpatient hospital stay during which the transplant was performed.

IV. Regulatory Impact Statement

Executive Order (E.O.) 12291 requires us to prepare and publish an initial regulatory impact analysis for any proposed regulation that meets one of the E.O. criteria for a "major rule"; that is, that would be likely to result in: An annual effect on the economy of \$100 million or more; a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or, significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets. In addition, we generally prepare an initial regulatory flexibility analysis that is consistent with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 through 612), unless the Secretary certifies that a proposed regulation would not have a significant economic impact on a substantial

number of small entities. For purposes of the RFA, individuals are not small entities, but we treat all pharmacists as small entities.

We have determined that the criteria for a "major rule" are not met and that a regulatory impact analysis is not required. Also, we have determined and the Secretary certifies that this proposed rule would not have significant economic impact on a substantial number of small entities. We have therefore not prepared a regulatory flexibility analysis.

V. Paperwork Reduction Act

These proposed changes would not impose information collection requirements; consequently, they need not be reviewed by the Executive Office of Management and Budget under the authority of the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et. seq.*).

VI. Response to Comments

Because of the large number of comments we receive on proposed regulations, we cannot acknowledge or respond to them individually. However, in preparing the final rule, we will consider all comments received timely and respond to the major issues in the preamble to that rule.

List of Subjects in 42 CFR Part 410

Medical and other health services, Medicare.

We are proposing to amend 42 CFR Part 410 as set forth below:

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

Subpart B—Medical and Other Health Services

Subpart B is amended as follows:

1. The authority citation for Subpart B continues to read as follows:

Authority: Secs. 1102, 1832, 1833, 1835, 1881(r), (s) and (cc), 1871, and 1881 of the Social Security Act (42 U.S.C. 1302, 1395k, 1395L, 1395n, 1395x, (r), (s) and (cc), 1395hh and 1395rr).

2. The table of contents is amended by adding a new § 410.65 to read as follows:

Sec.
§ 410.65 Immunosuppressive drugs.

2. In § 410.10, the introductory language is republished and a new paragraph (r) is added to read as follows:

§ 410.10 Medical and other health services: Included services.

Subject to the conditions and limitations specified in § 410.12, "medical and other health services" includes the following services:

(r) Immunosuppressive drugs.

3. In § 410.29, the introductory language is republished, and paragraph (a) is revised to read as follows:

§ 410.29 Limitations on drugs and biologicals.

Medicare Part B does not pay for the following:

(a) Except as provided in § 410.28(a) of this part, any drug or biological that can be self-administered, whether furnished by a physician, a provider of services, or other than a provider of services, except hemophilia clotting factors as provided in § 410.63(b), and immunosuppressive drugs as provided in § 410.65.

4. A new § 410.65 is added to read as follows:

§ 410.65 Immunosuppressive drugs.

Effective January 1, 1987, payment may be made for immunosuppressive drugs that have been approved for marketing by the Food and Drug Administration and either specifically labeled for the prevention or treatment of rejection of a transplanted organ or tissue, or identified in FDA-approved labeling for use in conjunction with immunosuppressive drug therapy. Coverage is available for immunosuppressive drugs furnished to an individual who receives an organ transplant for which Medicare payment is made, for a period of up to one year beginning with the date of discharge from the inpatient hospital stay during which the transplant was performed.

(Catalog of Federal Domestic Assistance Program No. 13.744, Medicare-Supplementary Medical Insurance Program)

Dated: July 15, 1987.

William L. Roper,
Administrator, Health Care Financing Administration.

Approved: October 22, 1987.

Otis R. Bowen,

Secretary.

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